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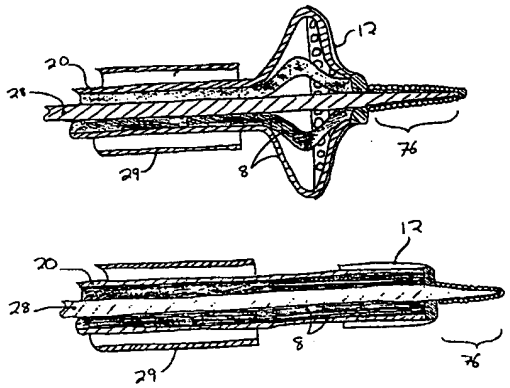
(54) Title: MEMBRANES FOR OCCLUSION DEVICE AND METHODS AND APPARATUS FOR REDUCING CLOGGING



(57) Abstract: There is provided a filter for use with a vascular occlusion device of the type having an elongated shaft and a number of radially expandable struts located near a distal end of said shaft. The filter comprises a hollow body made of a flexible material, with a proximal end and a distal end, and a region of maximum widthwise dimension located between the proximal end and the distal end. The body tapers from the proximal end to the region of maximum widthwise dimension and from the region of maximum widthwise dimension to the distal end. A number of pores are formed in the body, and the pores being sized to prevent emboli from flowing past the distal end when the filter is employed in the vasculature of a patient. Also disclosed are a web for preventing formation of thrombus on the struts of a vascular occlusion device, and a method for removing accumulated emboli from a filter.

WO 01/58382 A2

MEMBRANES FOR OCCLUSION DEVICE AND METHODS AND APPARATUS FOR REDUCING CLOGGING

Background of the Invention

Field of the Invention

This invention relates generally to the field of intravascular devices for filtering emboli from blood. More specifically, this invention relates to the design of mechanical occlusion or filter apparatus used in intravascular devices for filtering emboli from blood.

Description of the Related Art

Although attempts have been made to treat occlusions in the carotid arteries leading to the brain, such arteries have been very difficult to treat because of the possibility of dislodging plaque which can then enter various arterial vessels of the brain and cause permanent brain damage. Attempts to treat such occlusions with balloon angioplasty have been limited because of such dangers. In surgical treatments, such as endarterectomy, the carotid artery is clamped on either side of the treatment area, slit open and plaque is removed from the vessel in the slit area. Such surgical procedures, while being relatively safe from escape of emboli, nonetheless entail substantial risk.

In other procedures, such as in angioplasty and in the treatment of peripheral arteries and veins, there is the possibility that the delivery of the guide wires and catheters used in such procedures may dislodge plaque. When emboli or other particulates flow downstream to occlude blood flow in smaller vessels, they can cause serious damage, such as stroke. Thus, embolization and migration of micro-emboli downstream to an end organ is a major concern of cardiologists during catheterizations.

Various vascular filters have been proposed which would contain emboli produced as a result of intravascular procedures. However, the proper deployment of such filters remains problematic. For example, if a filter expands too far, damage to the vessel can result. Further, care must be taken when performing intravascular procedures that any interruption in the blood flow is temporary and minimal.

Thus, there remains a need for new and improved apparatuses and methods which make possible the treatment of occluded vessels without endangering the patient.

Summary of the Invention

The preferred embodiments of the present invention advantageously provide a filter for use with a vascular occlusion device of the type having an elongated shaft and a number of radially expandable struts located near a distal end of said shaft, wherein the filter comprises a hollow body made of a flexible material, with a proximal end and a distal end, and a region of maximum widthwise dimension preferably located between the proximal end and the distal end. The body tapers from the proximal end to the region of maximum widthwise dimension and from the region of maximum widthwise dimension to the distal end. A number of pores are formed in the body, with the pores being sized to prevent emboli from flowing past the distal end when the filter is employed in the vasculature of a patient.

In one preferred embodiment the filter comprises a cup made of a flexible material, the cup having a proximal end and a distal end, an opening at the proximal end, and a region of maximum widthwise dimension adjacent the opening. The cup tapers from the region of maximum widthwise dimension to the distal end. A number of pores are

formed in the cup, the pores being sized to prevent emboli from flowing past said distal end when said filter is employed in the vasculature of a patient.

In another preferred embodiment the filter comprises a first cup made of a flexible material, the first cup having a proximal end and a distal end, an opening at the proximal end, and a region of maximum widthwise dimension adjacent the opening. The first cup tapers from the region of maximum widthwise dimension to the distal end. The filter also has a second cup made of a flexible material, the second cup having a proximal end and a distal end, an opening at the distal end, and a region of maximum widthwise dimension adjacent the opening. The second cup tapers from the region of maximum widthwise dimension to the proximal end. The first cup has a first set of pores, the first set of pores being sized to prevent emboli from flowing past the distal end when the filter is employed in the vasculature of a patient. The second cup has a second set of pores wherein the first set of pores comprises pores which are smaller in diameter than the second set of pores.

In yet another preferred embodiment there is provided a vascular occlusion device comprising a shaft having a distal end and a proximal end, a filter subassembly attached to the distal end of the shaft and having a distal end and a proximal end. The filter subassembly comprises an expandable support and a filter suspended on the expandable support, and a distal tip comprising a coil attached to the distal end of the filter subassembly.

In yet another preferred embodiment, a method of removing accumulated emboli and thrombus from a vascular occlusion device comprises providing a vascular occlusion device with a shaft having a distal end and a proximal end, and a filter subassembly attached to the distal end of the shaft, the filter subassembly comprising an expandable support and a filter suspended on said expandable support; providing an aspiration catheter having a proximal end and a distal end, and advancing the aspiration catheter along the shaft until the distal end is in proximity to the filter subassembly; and applying a negative pressure to the proximal end of the aspiration catheter so as to remove thrombus and emboli by suction.

In still another preferred embodiment a method for catching emboli in a vessel comprises delivering a catheter having a filter on a distal end thereof, the filter comprising a cup made of a flexible material, wherein the cup has a proximal end and a distal end, an opening at the proximal end, and a region of maximum widthwise dimension adjacent the opening. The cup tapers from the region of maximum widthwise dimension to the distal end, and has a number of pores which are sized to prevent emboli from flowing past the distal end. The filter is expanded to take on a cross-sectional area substantially equal to that of the vessel at the location of the filter; and emboli are caught in the filter.

Brief Description of the Drawings

FIGURE 1 shows an isometric view of a shaft and filter subassembly deployed in a blood vessel, as well as a cut away view of a friction fit mechanism located proximal of the filter subassembly.

FIGURE 2A shows a top plan view of an adapter for use with the shaft and filter subassembly of FIGURE 1.

FIGURE 2B shows a perspective view of the adapter of FIGURE 2A in the open position.

FIGURE 3 shows a side view of the deployed filter subassembly including the struts and membrane of the filter as they would lie within a blood vessel.

FIGURES 3A and 3B show partial cut away side views of a laser cut hypotube with a pull wire and an outer retrieval hypotube in an expanded and collapsed configuration, respectively.

FIGURE 4 is a side elevation view of an occlusive member according to one embodiment of the invention.

FIGURE 4A is a side elevation view of an occlusive member according to another embodiment of the invention.

FIGURE 5 is a side elevation view of an occlusive member according to another embodiment of the invention.

FIGURE 6 is a side elevation view of a an occlusive member according to another embodiment of the invention.

FIGURE 7 is a side elevation view of an occlusive member according to another embodiment of the invention.

FIGURE 8 is a side elevation view of an occlusive member according to another embodiment of the invention.

FIGURE 9 is a side elevation view of a web for preventing formation of thrombus on the struts of a vascular occlusion device.

FIGURE 10 is a side elevation view of a structure and method for removing accumulated emboli from an occlusive member.

FIGURE 11 is a side elevation view of an occlusive member including two membranes on a single set of struts.

FIGURE 12 is a side elevation view of an occlusive member including a membrane on a single coiled wire.

FIGURE 13 is a side elevation view of an occlusive member including two coiled wires.

Detailed Description of the Preferred Embodiments

The following description and examples illustrate preferred embodiments of the present invention in detail. Those of skill in the art will recognize that there are numerous variations and modifications of this invention that are encompassed within its scope. Accordingly, the description of preferred embodiments should not be deemed to limit the scope of the present invention.

Overview of Occlusion Device

As illustrated in FIGURE 1, a preferred embodiment of the present invention comprises a shaft 70, a filter subassembly 1, and a guide tip 76. FIGURES 2A and 2B illustrate an adapter for use with a preferred embodiment of the present invention, which will be described below.

1. Shaft

As shown in FIGURE 1, the shaft 70 comprises an outer elongate member 20, and a core wire or pull wire 28 which extends through the lumen of the outer elongate member. The elongate member 20 may comprise a hypotube as is known in the art. Moreover, as described in assignee's copending application entitled STRUT DESIGN FOR AN OCCLUSION DEVICE, Serial No._____ [Attorney Docket No. PERCUS 106A], filed on the same day as the present application, the entirety of which is hereby incorporated by reference, multiple hypotubes may be coaxially disposed over the core wire 28. The shaft extends from a proximal end distally to the filter subassembly 1. The shaft may be constructed to any desired length, however, it is preferable for the shaft to be between about 120 to 200 cm in length.

The size of the outer member of the shaft 70 is suitable for insertion into the vasculature of a patient through an insertion site in the skin of the patient. It is preferable that the outer elongate member 20, the core wire 28, and any other hypotube members are disposed coaxially such that each member is located within any larger diameter member and surrounds any smaller diameter member.

It is preferable that the largest diameter member of the shaft, for example outer member 20 in FIGURE 1, has an exterior diameter of about 0.012 to 0.035 inches. It is more preferable that the largest diameter member of the shaft has an exterior diameter of about 0.014 to 0.018 inches. The wall thickness of the largest diameter hollow member of the shaft is preferably from about 0.001 to 0.005 inches, i.e. the diameter of the lumen of the largest hollow member of the shaft is preferably from about 0.002 to 0.010 inches less than the outer diameter of the member. Any members located within the largest diameter member are preferably sized so as to fit within the inner lumen of the larger member.

As shown in FIGURE 1, the outer member 20 of the shaft extends distally and is connected at its distal end to the filter subassembly 1. A core wire 28 is shown in FIGURE 1 and is used as the most centrally disposed of the shaft members. The core wire 28 is preferably a solid, i.e. non-tubular member around which the outer member 20 is disposed. The core wire 28 extends inside the outer member 20, through the filter subassembly 1, and into the guide tip 76 of the device.

The shaft members 20, 28 are preferably formed out of a material which is sufficiently strong to support the shaft 70 itself as well as the filter subassembly 1 at the distal end under tension, compression, and torsion which will be experienced when inserting, operating, and removing the device from the vasculature of a patient. The material is preferably also sufficiently flexible and elastic that it does not develop permanent deformation while being threaded through the curved path necessary to reach the treatment site from the insertion point.

In order to satisfy these requirements, it is preferable to use a metallic tube or wire to form the shaft members 20, 28, although a braided or non-braided polymer tube may also provide the desired characteristics. More preferably, a super-elastic memory alloy is used for the members, especially the core wire 28. Suitable alloys include nitinol and nitinol-stainless steel alloys. Additional suitable alloys include nitinol alloyed with vanadium, cobalt, chromium, niobium, palladium, or copper in varying amounts. Additional details not necessary to repeat here are disclosed in assignee's co-pending application entitled HOLLOW MEDICAL WIRES AND METHODS OF CONSTRUCTING SAME, Serial No. 08/812,876, filed on 6 March 1997, the entirety of which is hereby incorporated by reference.

2. FILTER SUBASSEMBLY

Still referring to FIGURE 1, filter subassembly 1, described in more detail below, extends from the distal end of the shaft 70. The filter subassembly 1 preferably comprises an expandable member which is either integrally formed (as described below) or separately attached (as shown in FIGURE 1) to the distal end of the shaft 70. The expandable member preferably includes an occlusive member 12 and support for this occlusive member.

As used herein, "occlusion" or "sealing", and the like, refer to blockage of fluid flow in a vascular segment, either completely or partially. In some cases, a complete blockage of the blood vessel may not be achievable or even desirable,

for instance, when blood flow must be maintained continuously to the region downstream of the occlusive device. In these cases, perfusive flow through the occluded region is desirable and a partial blockage is used. For example, a partial blockage may be produced using an occlusive member whose cross-sectional dimension does not span the entire blood vessel. Alternatively, a partial blockage may be produced using an occlusive member whose cross-sectional dimension does substantially span the entire blood vessel, but which contains openings or other means for flow to move through the occlusive member perfusively. In other cases, a partial blockage may not be achievable or desirable, and an occlusive member which substantially spans the cross section of the blood vessel without allowing perfusion is used. Each of these described structures makes use of "occlusion", as defined herein.

In the embodiment shown in FIGURE 1, the expandable member comprises struts 8 which extend from the distal end of the outer shaft member 20 to a plug 40 which is disposed distally of the distal end of the shaft 70. As used herein, "strut" refers to any mechanical structure which extends from another structure or which is used to support a membrane or other structure of the occlusion device. Specifically, as discussed herein, the struts of the occlusion device are those portions of the device which extend from the shaft in order to adjust the profile of the device as discussed below, and which may be used to support the membrane.

Still referring to FIGURE 1, core wire 28 extends past the distal end of member 20, beyond plug 40, and terminates in a solder joint 80 at the distal end of the distal tip. A tip 76 distal to the struts 8 preferably includes a radiopaque coil material 78 extending between the plug 40 and the solder joint 80 to aid the practitioner in positioning the expandable member 1 within the vessel 4.

A membrane 12 preferably extends over a distal portion of the struts 8 to the plug 40, such that when the expandable member is deployed, emboli are captured as blood flows toward that surface of the membrane 12 that faces the blood flow (the proximally facing surface), with blood exiting the distally facing surface of the membrane, leaving the embolic matter behind. This is shown in FIGURE 1. As used herein, "filter" and like terms mean any system which is capable of separating something out of a portion of the blood flow within the vascular segment, whether or not there is perfusion through the "filter". "Filtering" and similar terms refer to the act of separating anything out of a portion of the blood flow.

Further details not necessary to repeat here are disclosed in assignee's copending application entitled OCCLUSION OF A VESSEL, application Serial No. 09/374,741, filed on 13 August 1999, the entirety of which is hereby incorporated by reference.

3. PULL WIRE

The elongate member 20 surrounds the pull wire 28 and is attached to the struts 8 at their proximal end (see FIGURE 1). The pull wire 28 is advantageously attached to a plug 40 that is secured to the struts 8 at their distal end (e.g., by bonding), so that when the pull wire 28 is retracted relative to the elongate member 20, the plug 40 urges the struts 8 to expand in a radial direction. The pull wire 28 tapers such that the distal portions of the pull wire, especially those located beyond the plug 40, have a smaller cross section than the proximal portion of the pull wire. The relative position of the elongate member 20 and the pull wire 28 is varied until the vessel 4 is occluded. The struts 8 bow

outwards towards the wall of the vessel 4, so that the expandable member 1 seals the vessel 4 (i.e., in its deployed position, the expandable member prevents emboli from moving downstream). The radial expansion of the struts 8 may also be facilitated by advantageously imparting an initial curvature to the struts 8 through heat setting. The pull wire 28 may advantageously extend within the distal guide tip 76 beyond the plug 40 and terminate in a solder joint 80 at the distal end of the distal tip. The proximal end of the distal tip 76 may be advantageously secured to the plug 40.

After the expandable member 1 is deployed, the struts 8 tend towards their collapsed, undeployed position in the absence of a restraining force (unless the expandable member 1 is self-expanding, in which case the expandable member has a tendency to remain in the deployed position). To prevent the struts from returning to their undeployed position, the pull wire 28 has one or more bends 48 formed therein for contacting the inner wall of the elongate member 20, thereby providing frictional forces which keep the expandable member 1 in its expanded, deployed position, as shown in FIGURE 1. Specifically, the frictional force between the pull wire 28 and the elongate member 20 is sufficient to offset or compensate for the spring force provided by the struts 8, which would otherwise urge the struts towards their relaxed position. Whereas 0.5-1 pound of pulling force may be required to deploy the expandable member 1, the friction between the pull wire 28 and the elongate member 20 may be sufficient to restrain up to 3 pounds of pulling force. Thus, the bends 48 of the pull wire 28 engage the elongate member 20 to form a compact device for restraining the pull wire from unwanted longitudinal motion. The bends 48 of the pull wire 28 may be formed, for example, by coining or by forming a spring in the pull wire. The bends 48 thus act as a locking member which inhibits movement of the pull wire 28, and the pull wire 28 and the elongate member 20 are frictionally secured together. Additional details of this frictional locking mechanism not necessary to repeat here are disclosed in assignee's provisional application entitled METHODS AND APPARATUS FOR CONTROLLING EXPANSION OF AN OCCLUSION DEVICE, provisional application Serial No. _____ [Attorney Docket No. PERCUS.107PR], filed on 11 February 2000, the entirety of which is hereby incorporated by reference.

The pull wire features of the embodiment of FIGURE 1 can also be used if the expandable member 1 is shape set so that it tends toward an expanded, deployed position in the absence of any applied forces, i.e. if the expandable member is self-deploying. In the case where an embodiment such as that shown in FIGURE 1 is constructed using a self-deploying expandable member 1, the pull wire 28 effectively acts as a push-wire which holds the expandable member in the collapsed configuration. This push-wire is held in place by the frictional engagement between the bends 48 of the core wire and the outer elongate shaft member 20.

When using such a device as shown in FIGURE 1 with an expandable member which is self-deploying, the expandable member 1 is inserted into the vessel 4 of the patient in its low profile position, with frictional forces between the pull wire 28 and the elongate member 20 holding the core wire 28 in the distal direction, which prevents the expandable member from expanding. The expandable member 1 is then deployed by urging the pull wire 28 in the proximal, axial direction (retracting the pull wire) with sufficient force to overcome the frictional forces between the pull wire 28 and the elongate member 20, thereby moving the locking member 48 out of its locked position. In effect,

by moving the core wire proximally in this way, the "pushing" effect of the core wire is eliminated, and the expandable member will deploy into the expanded configuration.

The pull wire 28, shown in FIGURES 1 and 3, is manipulated through the use of an adapter or manifold which is attached to the proximal end of the shaft 70 (in FIGURE 3) of the device. The adapter (shown in FIGURES 2A and 2B and described below) enables the technician to control the relative positioning of the core wire 28 and the hypotube 20 in a simple manner. After delivery of the device to the desired location within the vasculature of the patient, the adapter is attached and the core wire 28 is manipulated through the use of the adapter so as to deploy the filter subassembly 72 (shown in FIGURE 3) or expandable member 1 (shown in FIGURE 1) of the device. At this point, the adapter may be removed from the device so that therapy may be performed. When the adapter is removed, the filter subassembly 72 remains in the deployed (expanded) configuration because of the friction lock mechanism described above which prevents inadvertent relative motion between the core wire 28 and the outer hypotube 20.

Although illustrated with respect to struts 8, the pull wire features of the embodiment of FIGURE 1 may be advantageously combined with any of the expandable members disclosed herein. Further details regarding the pull wire and locking mechanism not necessary to repeat here are disclosed in assignee's copending application entitled OCCLUSION OF A VESSEL, as referenced above.

4. ADAPTER

As shown in FIGURES 2A and 2B, an adapter is used in accordance with preferred embodiments of the present invention. Without regard to whether the expandable member is of the shape set variety (self-expanding) or is undeployed when relaxed, the degree to which the expandable member is deployed can be monitored by noting the longitudinal position of the pull wire 828, shown in FIGURE 2A. This allows the user to carefully control the extent to which the expandable member is deployed. A preferred adapter or manifold 900 for holding the elongate member 820 and for moving (i.e., both retracting and pushing out) the pull wire 828 is illustrated in FIGURE 2A. A thumb wheel 902 is used to control the position of the pull wire 828 relative to the elongate member 820, thereby controlling the extent to which the expandable member 1 of FIGURE 1 is expanded. As illustrated by the view of FIGURE. 2B, the manifold 900 includes two halves 904, 908 preferably formed of medical grade polycarbonate or the like.

A preferred adapter or manifold 900 for holding the elongate member 820 and for moving (i.e., both retracting and pushing out) the pull wire 828 is illustrated in the open position in FIGURE 2B. A thumb wheel 902 is used to control the position of the pull wire 828 relative to the elongate member 820, thereby controlling the extent to which the expandable member is expanded. As illustrated in FIGURE 2B, the manifold 900 includes two halves 904, 908 preferably formed of medical grade polycarbonate or the like.

The two halves 904, 908 are attached by at least one hinge 918, so that the halves are joined in a clam shell manner. A latch 920 secures the two halves 904, 908 while the manifold 900 is in use. The latch 920 includes a pair of flexible, resilient latching members 924, 926 (shown partially in phantom in FIGURE 2B) which are mounted within the half 908. A space 928 between the two latching members 924, 926 receives a locking pin 930 which has a beveled head 932. The head 932 passes through the space 928 and past the latching members 924, 926. The

latching members 924, 926 prevent the locking pin 930 from backing out past the latching members which would open up the manifold 900. To open the halves 904, 908, the latching members 924, 926 are separated slightly by depressing a flexure member 934, which pries apart the latching members slightly, thereby freeing the locking pin 930.

The elongate member 820 may be held in place by a groove (not shown) having a width selected to accept the elongate member 820. Alternatively, as shown in FIGURE 2B, the elongate member 820 and the pull wire 828 may be held by clips 832a, 832b, 832c, 832d having respective slots 833a, 833b, 834c, 834d therein for receiving the elongate member and the pull wire. In particular, the elongate member 820 and the pull wire 828 may be advantageously configured so that the elongate member rests within clips 832a, 832b, 832c, with the pull wire extending between the clip 832c and the clip 832d and extending proximal to the clip 832d. With this arrangement, and when the manifold 900 is in the closed position (see FIGURE 2A), the pull wire 828 may be engaged and moved by a first pair of contact members such as oppositely facing pads 950a, 950b, while the elongate member 820 is held stationary by one or more other pairs of oppositely facing pads 950c, 950d and 950e, 950f. (Alternatively, the device may be designed so that the elongate member 820 is moved while the pull wire 828 remains stationary.) The pads 950a-f may advantageously include a plurality of ridges 838 for securely contacting the pull wire 828. The clips 832a, 832b, 832c, 832d fit within respective cavities 836a, 836b, 836c, 836d in the manifold half 904 when the two halves 904, 908 are closed.

To aid the user in properly aligning the elongate member 820 and the pull wire 828 within the manifold 900, a mark may be placed on the elongate member 820. For example, an alignment mark on the elongate member 820 may indicate that point on the elongate member 820 which must be placed within the slot 833a so that the elongate member extends within the manifold 900 up to but not proximally beyond the clip 832c, with the pull wire 828 being exposed proximal to the clip 832c. This configuration permits the pads 950a, 950b to retract (or advance) the pull wire 828 into (or out of) the vessel while the elongate member 820 is held securely within the pads 950c, 950d and 950e, 950f.

When the pull wire 828 is not being advanced or retracted through the elongate member 820 by the pads 950a, 950b, relative movement of the pull wire and the elongate member is advantageously prevented by frictional contact between the bends 848 of the pull wire and an inner surface of the elongate member (see FIGURE 1). This permits the introduction of a therapy catheter (not shown) such as an angioplasty or stent catheter, or the exchange of a plurality of catheters, after the manifold 900 is decoupled and removed from the elongate member 820 and the pull wire 828, as discussed in more detail below. For example, once the expandable member is deployed, an angioplasty or stent catheter may be introduced over the elongate member 820 and the pull wire 828. After therapy is performed, an aspiration (and/or irrigation catheter) may be introduced over the elongate member 820/pull wire 828 to aspirate (and/or irrigate) away emboli entrained in the expandable member which were produced as a result of the therapy procedure. The manifold 900 may then be recoupled to the elongate member 820 and the pull wire 828, followed by deactivation (retraction) of the expandable member. The expandable member, the pull wire 828, and the elongate member 820 may then be removed from the vessel.

When the manifold 900 is in the closed position, the pads 950c, 950d and 950e, 950f (which are glued or otherwise fastened within recessed portions 954c, 954d and 954e, 954f of the manifold, respectively), surround and contact the elongate member 820 to prevent its motion. The pads 950a, 950b, on the other hand, are mounted in respective holders 956a, 956b which are slidable within respective recessed portions 953a, 953b of the manifold 900, so that when the pads 950a, 950b surround and contact the pull wire 828, the pull wire may be retracted or advanced. Specifically, the holder 956a (housing the pad 950a) is mechanically coupled to and controlled by the wheel 902, as discussed in more detail below. When the manifold 900 is closed, the pads 950a and 950b are compressed together and squeeze the pull wire 828 between them. As the user rotates the wheel 902, the pad 950a is moved in the longitudinal direction, and the pad 950b and the pull wire 828 are moved along with it. Thus, by rotating the wheel 902, the user may control the longitudinal position of the pull wire 828 with respect to the elongate member 820, and thereby control the extent to which the expandable member is radially deployed. The wheel 902 is visible through a slot 958 in the recessed portion 953a. The pads 950a-f may be C-Flex or Pebax and be 0.5-1.0" long, 0.25-0.5" wide, and 0.125-0.25" thick.

The wheel 902 imparts motion via a cam mechanism to the pad 950a which moves the pull wire 828 incrementally. The wheel 902 may advantageously move the pull wire 828, for example, between 3 mm and 20 mm as indicated by a dial 959 on the face of the wheel (see FIGURE 2A), thereby controlling the extent to which the expandable member is expanded by controlling the position of the pull wire. The dial 959 acts as a gauge of the relative longitudinal position of the pull wire 828 within the vessel, and thus as a gauge of the extent to which the expandable member has been expanded.

Additional details not necessary to repeat here are disclosed in assignee's copending application entitled OCCLUSION OF A VESSEL AND ADAPTER THEREFOR, application Serial No. _____ [Attorney Docket No. PERCUS.001CP4], filed on the same date as the present application, the entirety of which is hereby incorporated by reference.

The relative longitudinal position of the pull wire 828 within the outer tubular member 820 is maintained by frictional engagement means as described above and in assignee's provisional application entitled METHODS AND APPARATUS FOR CONTROLLING EXPANSION OF AN OCCLUSION DEVICE, as referenced above. These frictional engagement means may be advantageously used in a catheter exchange method in which the tubular, elongate member 820 functions as a guidewire. Catheters can be advanced over the tubular member 820 shown in FIGURE 2B by inserting the proximal end of the tubular member into a distal end of a lumen of the catheter. In one preferred method, the tubular member 820 is introduced into a vessel such that its distal end is distal of an occlusion to be treated. A therapy catheter (not shown), e.g. over-the-wire or monorail, having an angioplasty balloon at its distal end is advanced over the tubular member 820 until the balloon is positioned at the occlusion. An expandable device at the distal end of the tubular member 820 is mechanically actuated to occlude the vessel distal to the treatment site. Angioplasty is performed to open a stenosis at the treatment site while the vessel is occluded by the expandable member 1 (of FIGURE 1), e.g., by the expanded struts 8 surrounded by the membrane 12. The expandable device 1 prevents emboli

and other debris formed as a result of the therapy procedure from migrating downstream. The membrane 12 preferably allows for the perfusion of blood, while entraining or capturing larger particles.

After the angioplasty procedure is completed, the therapy catheter is withdrawn back over the tubular member 820 shown in FIGURE 2B and removed from the tubular member and the vessel. An aspiration and/or irrigation catheter (e.g. over-the-wire or monorail) is then introduced into the vessel by riding the aspiration (or irrigation) catheter over the tubular member 820 such that the tubular member is within a lumen of the catheter. With the expandable device 1 (of FIGURE 1) still deployed and the locking mechanism in its locked position, the aspiration (irrigation) catheter is advanced over the tubular member to the treated site, so that the distal end of the catheter is at a location distal to the treated occlusion and proximal to the expandable device 1. Suction is then applied at the proximal end of the catheter to remove emboli and other debris from the treated site, e.g., particles that are lodged against the proximally facing surface of the membrane 12. Such suction creates a distal to proximal blood flow through the lumen of the aspiration catheter and a proximal to distal blood flow in the annular region between the catheter and the blood vessel. (If the expandable device 1 has holes therein for the perfusion of blood, such suction may also create distal to proximal blood flow through the expandable device.) The site may, if desired, also be irrigated through the aspiration catheter by applying irrigation fluid rather than suction at the proximal end. While the preferred method involves exchange of an angioplasty (or stent) catheter and an aspiration catheter, it will be understood that any number of catheters may be exchanged without deactivating the expandable device 1. Additionally, the expandable device 1 may be placed inside the aspiration (irrigation) catheter following treatment and removed from the patient. This may reduce the risk of the expandable member being entangled with a stent or the vessel itself.

As shown in FIGURE 1, the foregoing exchange of catheters is facilitated by the locking member 48 on the proximal end of the pull wire 28, which does not extend radially outwardly beyond the outer periphery or circumferential extent of the tubular member 20. Accordingly, when the locking member 48 is in its locked position, the lock lies within the profile of the tubular member 20, thereby permitting the catheters to be slid over the tubular member without unlocking or otherwise disturbing the lock (i.e., without changing the lock's position).

After all of the desired catheters have been utilized and removed, the expandable device 1 shown in FIGURE 1 is collapsed and the tubular member 20 is withdrawn from the vessel. Thus, the expandable member 1 is expanded prior to initiation of any treatment which may dislodge occlusive material and create emboli, and the expandable device 1 is not collapsed until preferably all emboli have been removed or captured.

Additional details not necessary to repeat here are disclosed in assignee's copending application entitled EXCHANGE METHOD FOR EMBOLI CONTAINMENT, application Serial No. 09/049,712, filed on 27 March 1998, the entirety of which is hereby incorporated by reference.

STRUT DESIGN

Another preferred embodiment of a filter assembly in accordance with the current invention is shown in FIGURE 3. The filter subassembly 72 is located along the shaft 70 near the distal end, and proximal of the guide tip

76. The filter subassembly is preferably integrally formed with the outer member 88 of the shaft 70. The filter subassembly 72 comprises a number of struts 82 and an occlusive membrane 74. The struts support the occlusive membrane, as well as providing for at least two configurations of the device, a collapsed configuration and an expanded configuration. The expanded configuration is shown.

The "collapsed" configuration refers to the lowest profile configuration of the struts. In this context, "profile" refers to the distance away from the axis of the device that is spanned. Therefore, "low profile" refers to configurations in which the device is entirely within a small distance from the axis of the device. The "collapsed configuration" is the configuration in which the struts have the lowest possible profile, that is, where they lie as close as possible to the axis of the device. Having a low profile configuration simplifies insertion and removal of the device, and strut designs which tend to reduce the profile of the occlusion device are advantageous.

In the collapsed configuration, the embodiment shown in FIGURE 3 would have the struts 82 and the occlusive member 74 positioned such that they were disposed as close as possible to the longitudinal axis of the device, i.e. they would have the smallest possible cross-section. This configuration facilitates the deployment of the filter subassembly 72 by delivering it through the blood vessel 86 on the distal end of a catheter shaft, as well as the retrieval of the filter subassembly 72 at the conclusion of the procedure. By minimizing the profile of the filter subassembly, this configuration is more easily passed through the vasculature leading to the filtration site from the insertion point.

When moved from the expanded configuration, shown in FIGURE 3, into the collapsed configuration, the occlusive member 74 may not lie in the same profile as it did prior to deployment into the expanded configuration. This is because the occlusive member is being retracted strictly by the action of the struts, and excess folds of material may extend from between the struts in the collapsed configuration. This may cause the profile of the filter subassembly 72 to be larger after retraction than it was prior to deployment. This enlarged profile can cause the occlusive member 74 to rub against the vessel walls in an undesirable manner. One way to address this difficulty is to use a retrieval catheter as shown in FIGURES 3a and 3b and described below.

In the "expanded" configuration shown in FIGURE 3, the struts 82 and the occlusive member 74 are positioned such that they span substantially the entire width of the blood vessel 86 in which they are positioned. This is preferably the highest profile possible for the struts within the blood vessel. This configuration facilitates the use of the filter subassembly 72 to trap embolic matter while permitting passage of blood through the filter subassembly. By providing a means to span substantially the entire width of the blood vessel 86 to be filtered, the struts 82 support the occlusive member 74 in a configuration which forces the blood flow through the vessel to pass through the pores or openings in the filter subassembly 72 while retaining emboli therein. This produces the desired filtering effect.

In one embodiment the struts are preferably formed by laser cutting slits in a hypotube. Some preferred materials for the hypotube include nitinol, nitinol/steel alloys, and stainless steel. Generally, the same materials as described above for use in the shaft are also preferred for use in the struts. For example, in one preferred embodiment, a nitinol hypotube with a diameter of .018" is used. The hypotube is laser cut in a spiral configuration to provide for

struts which take a spiral shape when adjusted into the expanded configuration, as described below. Alternative preferred embodiments have straight slits which provide for non-spiral struts when deployed into the expanded configuration.

Actuation of the struts in order to adjust the device from the collapsed configuration to the expanded configuration (shown in FIGURE 3) is achieved using either a tension or a torsion mechanism. In tension based actuation, the core wire 28 is displaced axially within the hypotube 88 in a proximal direction. In one preferred embodiment, this displacement allows the struts to expand under a built-in bias into the expanded configuration. In the embodiment shown in FIGURE 3, the displacement applies an outward biasing force to the struts. In torsion based actuation, the core wire 28 is rotated with respect to the hypotube 88, resulting in a rotational displacement which applies an outward biasing force to the struts. In order to adjust from the expanded to the collapsed configuration, the actuation is reversed, by either pushing or rotating the core wire in the opposite direction from that used in the deployment, reversing the force upon the struts, and returning the device to the original configuration.

Additional details not necessary to repeat here are disclosed in assignee's copending application entitled STRUT DESIGN FOR AN OCCLUSION DEVICE, application Serial No. _____, [Attorney Docket PERCUS.106A] filed on the same date as the present application, referenced above.

1. GUIDE TIP

As shown in FIGURE 1, located most distally upon the shaft 70 is a guide tip 76. The guide tip lies distal of the filter subassembly 1 and provides a flexible leading extension which bends to follow the curvature of the blood vessels 4 through which the device is advanced. By bending to follow the wall of the blood vessel, the guide tip 76 leads the filter subassembly 72 and other more proximal elements of the device in the direction of the tip so as to make the device move through the vessel without excessive impact against the walls of the blood vessels 4 of the patient.

With reference to FIGURE 3, in one embodiment the guide tip 76 is formed by creating a rounded solder joint tip 80 to the core wire 28 of the shaft 70, and wrapping it in a thinner wire to produce a coil 78 which provides a spring force between the filter subassembly 72 and the rounded tip 80. The wire used for the coil 78 is preferably made of a radiopaque material. Because the core wire 28 is constructed of a flexible material, such as nitinol, it will bend when the rounded tip 80 is pushed against the curving wall of a blood vessel 86. However, as the deflection of the tip increases, the spring force of the coil of thinner wire 78 will attempt to pull the filter subassembly 72 and shaft 70 into alignment with the guide tip 76. In this way, the entire shaft is made to follow the path of the guide tip 76 as it advances through the blood vessels toward the treatment site.

2. MEMBRANE

As seen in FIGURE 3, the occlusive member or membrane 74 is preferably attached to each of the struts 82 and extends completely around the longitudinal axis of the device. Preferably, the occlusive member 74 is attached to the outer surface of the struts 82; however, it may be attached along the inside of the struts 82 as well. Moreover, it will be appreciated that the filter membrane may be provided inside some of the struts and outside of others. It will

also be appreciated that struts may be provided on both sides of the membrane in a sandwiched configuration, or that two membranes may sandwich a set of struts.

At its distal end the occlusive member 74 is joined to the radiopaque coil 78. As the occlusive member 74 can be constructed in varying lengths, its proximal end may be located between the midpoint and the proximal end of the struts 82. Where the occlusive member 74 extends along the entire length of the struts 82 it may also be attached at its proximal end to the distal end of the shaft 70. Thus, when the struts 82 are radially expanded, the occlusive member 74 will likewise expand so as to take on a cross-sectional area corresponding approximately to that of the internal dimensions of the blood vessel 86. It is contemplated that the occlusive member can be joined to the struts 82, coil 78, and/or shaft 70 by employing standard attachment methods, such as heat fusing, adhesive bonding, etc.

As shown in FIGURE 3, one preferred occlusive member 74 is a nonelastomeric membrane with a number of pores which are approximately 20-100 microns in diameter. Suitable nonelastomeric materials include, but are not limited to: polyurethane, polyethylene, polyethylene terephthalate (PET), expanded polytetrafluoroethylene (PTFE), and polyether-based polyamides sold under the trade name PEBAX by Elf Atochem. This type of occlusive member may be extruded or dip molded, with the pores formed by the mold itself, or subsequently using an excimer laser or other drilling process.

One suitable elastomeric material is a block copolymer of styrene-ethylene-butylene-styrene (SEBS), available under the trade name C-FLEX, sold by Consolidated Polymer Technologies. The membrane may also be made from latex or silicone. The occlusive member may alternatively comprise a polymer mesh of polyurethane, nylon, polyester, or polyethylene, with pores approximately 30-50 microns in diameter. Yet another alternative is a braid of polyester or nitinol. To prevent formation of blood clots on the occlusive member, it may be coated with heparin or other known antithrombogenic agents such as hirudin or pirudin.

A variety of pore configurations are suitable for use with the occlusive member. First, where the membrane 74 extends along the entire length of the struts, about 2-10 pores of about 20-200 microns diameter may be arranged longitudinally along the occlusive member. Another suitable configuration for this type of occlusive member consists of several pores of about 20-200 microns in diameter on the distal half of the member, and large triangular, round, or square cutouts on the proximal half. Alternatively, the entire surface of the occlusive member may have pores of about 20-200 micron size. This configuration is also contemplated for use where the occlusive member 74 has an open proximal end. When using this type of occlusive member, a non-permeable cover or web may be placed over the juncture of the proximal ends of the struts to the distal shaft, to prevent formation of thrombi in the narrow passages formed at this point.

The device may also employ dual occlusive members on a single set of struts, with a proximal filter with relatively large pores and a distal filter with smaller pores. With any of the mentioned types of occlusive member, it is contemplated that an aspiration catheter may be employed to remove thrombi from the filter(s) at various points in an angioplasty or other similar procedure.

3. OPERATION

The use of the described embodiments of the instant invention will generally be part of a process of therapy on a portion of the blood vessel of a patient. Usually, the therapy will involve treatment of some form of blockage of the blood vessel. However, those skilled in the art will recognize that the use of the described invention is appropriate in any situation where there is a possibility of embolic matter being dislodged from the vasculature of the patient, and therefore a desire to inhibit the dispersal of such embolic matter into the bloodstream of the patient.

As used herein, "method" refers to a preferred sequence used to accomplish a goal. Furthermore, the method which is described below is not limited to the exact sequence described. Other sequences of events or simultaneous performance of the described steps may be used when practicing the instant invention.

First, the device is manipulated so that the filter subassembly or subassemblies are in the collapsed position. This simplifies the insertion of the device into the blood stream of the patient. The device is then inserted through an insertion site into a blood vessel of the patient. Once inserted into the vasculature of the patient, the device is advanced distally until the distal portion of the device is located adjacent to the region of the blood vessel to be treated.

The device is positioned such that the filter subassembly lies generally downstream of the treatment site, or more generally, such that the filter subassembly lies between the treatment site and any site which is of particular susceptibility to embolic damage (e.g., the brain or coronary arteries). In this way, the filter is positioned so as to intercept any embolic matter dislodged at the treatment site, before such embolic material can reach any vulnerable area or be dispersed through the blood flow of the patient.

Once in position, the filter subassembly is actuated so that it assumes its expanded configuration, effectively occluding the blood vessel so that all blood flow must pass through at least one of the filter membranes or other occlusive members of the device.

The desired therapy is now performed upon the region of the blood vessel to be treated. This may involve placement or removal of support stents, balloon angioplasty, or any other vascular therapy that is conducted through the use of interventional techniques. In the course of such interventional treatment, additional catheters or other devices may be introduced to the treatment area by threading them over or along the shaft of the occlusive device. During the therapy, any embolic matter which is dislodged will flow into the filter and be caught by the membranes supported by the struts.

At any point during the therapy, the embolic matter may be aspirated from the filters through the use of separate aspiration catheters or through the lumen of the outer hypotubes forming the shaft of the occlusive device. Such aspiration may be repeated as often as necessary to maintain perfusive blood flow through the filter subassembly and treated region.

When the therapy is concluded, the filter subassembly is retracted into its collapsed configuration by reversing the actuation process. This will return the struts to a low profile which can then be withdrawn from the patient through the insertion site.

FIGURES 3A and 3B illustrate one embodiment in which struts 8 are laser cut into a middle hypotube 20. The distal end of the struts 8 is preferably crimped onto a core wire or pull wire 28 which is tapered toward its distal end. To actuate or deploy the filter subassembly, the core wire is pulled in relation to the middle hypotube 20 to expand the struts 8 with membrane 12. To retract the filter, the core wire is pushed distally, and the middle hypotube is pulled such that the struts collapse down into the optional retrieval hypotube 29. By retracting the filter subassembly through the retrieval hypotube 29, the blood vessel is protected from damage while the device is removed from the body. This is especially advantageous because the filter membrane 12 often has a larger profile after particles are trapped therein. This larger profile filter may scrape against the walls of the vessel if extracted without a retrieval hypotube.

It will be appreciated that the retrieval hypotube 29 is optional in the above embodiment. It will also be appreciated that the retrieval hypotube may take the form of an aspiration catheter which is used prior to removal of the device to aspirate particles trapped within the membrane. Thus, in one embodiment, the filter subassembly is removed through the lumen of the aspiration catheter.

MEMBRANE

As seen in FIGURE 3, the occlusive member or membrane 74 is attached to each of the struts 82 and extends completely around the longitudinal axis of the device. Preferably, the occlusive member 74 is attached to the outer surface of the struts 82; however, it may be attached along the inside of the struts 82 as well. At its distal end the occlusive member 74 is joined to the coil 78 (or the plug 40 as seen in FIGURE 1). As the occlusive member can be constructed in varying lengths, its proximal end may be located between the midpoint and the proximal end of the struts 82. Where the occlusive member extends along the entire length of the struts 82 it may also be attached at its proximal end to the distal end of the shaft 70 (see FIGURES 4-6). Thus, when the struts 82 are radially expanded, the occlusive member will likewise expand so as to take on a cross-sectional area corresponding to that of the internal dimensions of the blood vessel 86. It is contemplated that the occlusive member can be joined to the struts 82, coil 78, and/or shaft 70 by employing standard attachment methods, such as heat fusing, adhesive bonding, etc.

As shown in FIGURES 4-10, one preferred occlusive member 74 is a nonelastomeric membrane with a number of pores which are approximately 20-200 microns in diameter. Suitable nonelastomeric materials include, but are not limited to: polyurethane, polyethylene, polyethylene terephthalate (PET), expanded polytetrafluoroethylene (PTFE), and polyether-based polyamides sold under the trade name PEBAX by Elf Atochem. This type of occlusive member may be extruded or dip molded, with the pores formed by the mold itself, or subsequently using an excimer laser or other drilling process. One suitable elastomeric material is a block copolymer of styrene-ethylene-butylene-styrene (SEBS), available under the trade name C-FLEX, sold by Consolidated Polymer Technologies. One recognized advantage of an elastomeric occlusive member, or an occlusive member made of other materials of high elasticity, is that such an occlusive member can assume the retracted position without significant gathering or folding between the struts. Thus, the elastomeric occlusive member can be relatively taut around the struts when in the retracted state, and stretched circumferentially by the struts when expanded to occlude a vessel. The occlusive member may also be

made from latex or silicone, or alternatively comprise a polymer mesh of polyurethane, nylon, polyester, or polyethylene, with pores approximately 30-50 microns in diameter. Yet another alternative is a braid of nylon, polyester or nitinol. To prevent formation of blood clots on the occlusive member, it may be coated with heparin or other known antithrombogenic agents such as hirudin or pirudin.

A variety of pore configurations are suitable for use with the occlusive member. FIGURE 4 shows an occlusive member 74 comprising a balloon 102 attached to and suspended on the struts 82. The balloon 102 extends the entire length of the struts 82, and attaches to the distal end of the shaft 70 and to the proximal end of the coil 78. The line A-A marks a region of maximum widthwise dimension of the occlusive member 74. Here the occlusive member 74 has its largest cross-sectional area (taken at right angles to the longitudinal axis of the occlusive member 74) when deployed, wherein the surface of the occlusive member 74 is preferably firmly positioned against the vessel walls 86. Firm contact with the vessel walls 86 prevents blood flow around the occlusive member 74, forcing substantially all of the blood to pass through it. This maximum widthwise dimension and maximum cross-sectional area may prevail along an extended longitudinal portion of the occlusive member 74, resulting in an extended region 103 of maximum width between the distal and proximal extremities of the occlusive member 74. The occlusive member has a tapered proximal face 104 proximal of the line A-A and a tapered distal face 106 distal of the line.

In one configuration, shown in FIGURE 4, the occlusive member 74 has a number, preferably about 2-10, of pores 108 arranged in one or more lines extending longitudinally along the balloon surface. The pores 108 are preferably about 20-200 microns, more preferably about 30 to 100 microns, in diameter. ("Diameter," as used with reference to the pores 108, refers to widest dimension of a given pore and is not intended to restrict the pores 108 to a circular shape. While rounded shapes, i.e., oval or circular, are advantageous, the pores 108 may take on a variety of shapes within the defined dimensional restrictions.) To permit the occlusive member 74 to function properly, at least one pore 108 is preferably located on the proximal face 104, and at least one pore 108 is preferably located on the distal face 106. Otherwise, blood may not flow through the occlusive member 74, possibly eliminating any advantages of perfusion.

FIGURE 4A shows another configuration of the occlusive member 74 which also illustrates the perfusion aspect in detail. This embodiment features a number of longitudinally arranged pairs of pores 108, with each pair comprising a pore 108 on the proximal face 104 and a corresponding pore 108 on the distal face 106. The longitudinal alignment of each pair facilitates perfusion through the occlusive member 74 along an imaginary channel 109 "connecting" each pore in a given pair.

FIGURE 5 shows another configuration of the occlusive member 74 comprising a balloon 102 situated on and attached to the struts 82 and attached to the shaft 70 and coil 78. This type of occlusive member also has pores 108 formed in the balloon surface, but in contrast to the configuration shown in FIGURE 4 the pores 108 are distributed evenly across substantially the entire occlusive member 74. Thus, it is easily seen that there is at least one pore 108 located on both the proximal and distal faces 104, 106 of the occlusive member 74, facilitating perfusion.

FIGURE 6 shows another embodiment of the occlusive member 74 formed from a balloon 102 extending substantially the full length of the struts 82 from the shaft 70 to the coil 78. On the distal face 106 are a number of pores 108 distributed evenly across the balloon surface. The proximal face 104 has a number of relatively large cutouts 110 which may be triangular, round, square or any other suitable shape. This configuration provides dual-stage filtration of emboli, with a relatively coarse filter on the proximal face 104 and a relatively fine filter on the distal face 106. This type of occlusive member also permits (all but the largest) emboli to enter the interior of the occlusive member 74 and accumulate therein, which may often be desirable for the removal of the device and emboli from the vasculature of the patient.

FIGURE 7 shows another configuration of the occlusive member 74 comprising a cup 112 constructed of similar materials as may be used to form the balloon 102 disclosed previously. The cup 112 is distinguished in that its proximal end begins distal of the distal end of the shaft 70. Thus the cup 112 has an opening 114 at its proximal end. The cup 112 extends distally from the opening 114 along the struts 82 to the coil 78. Preferably, the cup 112 is attached to the struts 82 and coil 78 in a manner similar to the attachment of the balloon 102 to the same structures. In FIGURE 7 line B-B marks a region of maximum widthwise dimension of the struts 82 when deployed. Preferably, the cup 112 extends sufficiently proximally along the struts 82 that the opening 114 is situated on or proximal of line B-B, so that the outer surface of the cup 112 contacts the vessel walls 86. It is also desirable (though not necessary) that the opening 114 has a perimeter which is at right angles to the longitudinal axis of the occlusive member 74. As with the other embodiments of the occlusive member 74, the cup 112 has a number of pores 108 which permit perfusion through the occlusive member 74. Like the occlusive member shown in FIGURE 6, this embodiment also permits emboli to accumulate in the interior of the occlusive member 74, a performance aspect which may be desirable for certain procedures.

FIGURE 8 shows another variation of the occlusive member 74 which employs a pair of cups. This occlusive member 74 has a distal cup 116, which may be similar in structure, location and orientation to the cup 112 described above with reference to FIGURE 7, and a proximal cup 118. The proximal cup 118 is longitudinally inverted relative to the distal cup, so that its opening 120 forms its distal end. The two cups 116, 118 are preferably spaced apart from each other, in one embodiment, by a distance of about 5 mm. This spacing provides a manufacturing advantage. Preferably, the proximal cup 118 has pores 122 which are larger in diameter than the pores 108 on the distal cup 116. As with the embodiment shown in FIGURE 6, this configuration facilitates dual-stage filtration, wherein the blood passes first through the coarse filter of the proximal cup 118 and then through the fine filter of the distal cup 116.

FIGURE 9 depicts structure which may be employed to reduce or prevent thrombus formation on the device when deployed in a blood vessel. The occlusive member 74, when in the form of a cup 112, leaves the proximal extent of the struts 82 exposed to blood flow. Thus the blood flow passes through narrow gaps 124 formed between the struts 82 where they meet the distal end of the shaft 70. A proximal web 126, made of similar materials as disclosed for the occlusive member, may be attached to the struts 82 where they meet the distal end of the shaft 70. Preferably, the web 126 is nonporous and covers only that extent (about 0.25 inches) of the struts 82 as is necessary

for prevention of thrombus formation; otherwise the web 126 may undesirably impede the flow of blood into the occlusive member 74. It is contemplated that the web 126 can be attached to the struts 82 and/or shaft 70 by the same techniques used for attachment of the occlusive member 74 itself.

Another embodiment which prevents thrombus formation around the occlusive member 74 is the use of antithrombogenic agents such as heparin, hirudin or pirudin. The occlusive member 74 may be partially or completely coated with one of these agents to prevent thrombus formation thereon. However, such a coating can alter the size of the pores 108; this tendency makes it desirable to coat only any nonporous portions of the occlusive member 74. Desirably, the struts 82 and/or web 126 may have an antithrombogenic coating as well.

FIGURE 10 shows another embodiment which manages the formation of thrombus around the occlusive member 74, and removes accumulated emboli from it. At selected times during deployment of the occlusive member 74, an aspiration catheter 128 may be introduced (preferably by advancing it along the shaft 70) and its distal end 130 positioned near the occlusive member 74 to remove any thrombus or emboli by suction. Desirably, the aspiration catheter 128 in one embodiment is a 5.4 French to 8 French size, with a preferred size of 7 French. The distal portion 132 of the aspiration catheter 128 is preferably high density or low density polyethylene blend, or alternatively polyethylene joined to a proximal portion (not shown) of braided or non-braided polyimide, or polyetheretherketone (PEEK). However, it is contemplated that other types of aspiration catheter may be used as well.

With the aspiration catheter 128 deployed as shown, preferably about 0 to 1 cm from the proximal end of the struts, a negative pressure may be applied at the proximal end (not shown) to draw any nearby emboli or thrombus from the struts 82 and occlusive member 74 into the distal end 130. It is contemplated that this procedure is performed from time to time after initial deployment of the occlusive member, to prevent accumulated emboli from blocking the pores 108, which blocking can inhibit perfusion. In addition, it is often desirable to remove emboli from the occlusive member before withdrawing it from the patient; when retracted the occlusive member will often take on a higher profile with a large accumulation of emboli inside of it. Such a higher profile can impede easy removal of the occlusive member from the patient. Although FIGURE 10 shows an occlusive member 74 in the form of a cup 112, this aspiration technique is suitable for use with any of the embodiments of the occlusive member 74 disclosed above. Further details on aspiration catheter design are disclosed in Assignee's copending application titled ASPIRATION SYSTEM, Application Serial No. 09/026,013, filed February 19, 1998, the entire contents of which are incorporated herein by reference.

The aspiration catheter described above may also be advantageously used as a retrieval sheath for removing the occlusive member 74 after treatment is complete. Because the occlusive member 74 is often filled with particles after treatment, the occlusive member can preferably be removed through the lumen of the aspiration catheter to prevent the occlusive member from contacting thrombus or the walls of the vessel. This thereby prevents damage to the occlusive member as well as to the vessel.

Various techniques may be employed to form the occlusive member 74, including extrusion and dip molding. As a first step in an extrusion-forming process, the selected occlusive member material is extruded into a tube which

will subsequently be shaped into a balloon. Additional details on the balloon forming process are recited in Assignee's copending application titled BALLOON CATHETER AND METHOD OF MANUFACTURE, Application Serial No. 09/026,225, filed February 19, 1998, the entire contents of which are incorporated herein by reference. Any suitable one inch extrusion apparatus may be used to form the extruded tubes. After extrusion, the tube has an inner diameter much larger than the outer diameter of the shaft 70. To reduce the tubing inner diameter as necessary, it is stretched longitudinally such that the inner diameter decreases to about .002-.003 inches greater than the outer diameter of the shaft. The stretched tubing is cut to appropriate balloon length and bonded to the shaft. Tapered portions may be added by conventional means known to those of skill in the art, such as adhesive bonding of the tapered portions separately to the shaft after the balloon has been attached. Alternatively, tapered portions can be formed by adhesives which are applied to the balloon. In addition, it is possible to blow mold the balloon with a taper and then attach it. A balloon may also be formed by a dip molding process.

After the balloon is formed, an excimer laser or other drilling apparatus may be used to drill the desired pores in the balloon. After drilling, the balloon is cut as necessary. For example, with a cup type occlusive member (see FIGURE 7) the balloon is cut widthwise to create the opening 114. The balloon may also be cut lengthwise into two halves for easier bonding to the shaft 70 and struts 82.

Suitable techniques for joining the occlusive member to the shaft 70 and struts 82 include adhesive bonding and heat fusing, as known to those of skill in the art. A primer, such as 7701 LOCTITE, available from Loctite Corp., may be used to improve the bonding of the occlusive member to nitinol. Other details relevant to bonding may be found in Assignee's copending patent application Serial No. 09/026,225, incorporated by reference above.

It will be appreciated that other configurations are contemplated for the occlusive member 74. Examples of other configurations are shown in FIGURES 11-13. FIGURE 11 illustrates, for instance, two occlusive members 74a, 74b mounted over a single set of struts 82. Each of the occlusive members 74a, 74b may be of the type having an open proximal end, like the cup 112 described above with respect to FIGURE 7. One or both of the occlusive members 74a, 74b may have a region of maximum widthwise dimension 103 where the occlusive members fit tightly against the vessel wall, conforming to its cross-section.

The proximal occlusive member 74a attaches to (preferably each of) the struts 82 at points 140 near its proximal end, and to the coil 78 or the block 40 at its distal end. FIGURE 11 shows the proximal occlusive member 74a attached to the outside of the struts 82 at points 140, which requires each strut 82 to intersect the occlusive member 74a distal of each point 140. Alternatively, the proximal occlusive member 74a could attach to the inside of the struts 82 at points 140. The distal occlusive member 74b attaches to the struts 82 and the coil 78 or the block 40 in a similar manner as described above with reference to the cup 112 in FIGURE 7, but preferably positioned over the proximal occlusive member on the coil 78/block 40. Each of the proximal and distal occlusive members 74a, 74b preferably has a number of pores 108a, 108b. Advantageously, the pores 108a in the proximal occlusive member 74a are larger than the pores 108b in the distal occlusive member 74b, so as to permit the "dual-stage" filtration performance described above with respect to FIGURE 8.

The struts 82 depicted in FIGURE 11 operate in the same manner as disclosed previously. When the struts 82 open to the deployed position as shown, they expand and hold open the open proximal end of each of the proximal and distal occlusive members 74a, 74b, which catch any emboli in the blood flowing through them. When the struts 82 are retracted, the proximal occlusive member 74a folds closely against the centerline of the device. At the same time, the distal occlusive member 74b folds closely on top of a portion of the proximal occlusive member 74a

FIGURE 12 illustrates an occlusive member 74 mounted over a coiled wire 282. The coiled wire 282, preferably made of a shape-memory alloy such as nitinol, is wrapped around a core wire 228, and is preferably pre-set and shaped into a desired expanded configuration. The core wire 228 is disposed within and is preferably longitudinally and/or torsionally moveable relative to an outer tubular member 270. The coiled wire 282 is anchored at its proximal end to the outer tubular member 270 and at its distal end to the core wire 228. Advantageously, the core wire 228 and outer tubular member 270 may be structurally similar to the pull wire 28 and shaft 70 disclosed at length above.

Movement of the core wire 228 in the proximal direction relative to the outer tubular member 270 slackens the coiled wire 282 and permits it to assume the pre-set expanded configuration, deploying the occlusive member 74 for use. Naturally, movement of the core wire 228 in the distal direction stretches the coiled wire 282 and retracts it and the occlusive member into the contracted position close to the centerline of the device. Alternatively, this slackening/stretching action can be achieved by twisting one or both of the core wire 228 and the outer tubular member relative to one another. Figure 13 shows a coiled-wire mechanism similar to that shown in Figure 12, but depicts an alternative embodiment with two coiled wires 282a, 282b over a core wire 228. This embodiment permits both "longitudinal" and "torsional" deployment as detailed above, where both coiled wires 282a, 282b, are coiled in the same direction, i.e. clockwise or counterclockwise relative to the core wire 229.

It is also contemplated that the various embodiments of the occlusive member disclosed herein are suitable for deployment near the end of a catheter by using mechanisms other than the strut configuration described above. For example, the occlusive member can be deployed at the end of an assembly of flexible, threadlike leads in the manner of a parachute, and maintained in the deployed position by the pressure of blood flow into or through it. As a further alternative, the occlusive member can be deployed on a network of inflatable struts, which comprise hollow flexible members that assume a more rigid state when inflated with a fluid.

Other details on the construction of occlusive members not necessary to repeat here are disclosed in assignee's copending application entitled OCCLUSION OF A VESSEL, application Serial No. 09/026,106, filed Feb. 19, 1998, the entirety of which is hereby incorporated by reference.

Although this invention has been disclosed in the context of certain preferred embodiments and examples, it will be understood by those skilled in the art that the present invention extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the invention and obvious modifications and equivalents thereof. Thus, it is intended that the scope of the present invention herein disclosed should not be limited by the particular disclosed embodiments described above, but should be determined only by a fair reading of the claims that follow.

WHAT IS CLAIMED IS:

1. A filter for use with a vascular occlusion device of the type having an elongated shaft and a filter deployment system located near a distal end of said shaft, said filter comprising:

a hollow body made of a flexible material, said body having a proximal end and a distal end, said body having a region of maximum widthwise dimension located between said proximal end and said distal end, said body tapering from said proximal end to said region of maximum widthwise dimension and from said region of maximum widthwise dimension to said distal end; and

a number of pores in said body, said pores being sized to prevent emboli from flowing past said distal end when said filter is employed in the vasculature of a patient;

wherein said number of pores comprises 2-10 pores arranged in at least one row situated longitudinally along said body, at least one of said pores being located proximal of said region of maximum widthwise dimension and at least one of said pores being located distal of said region of maximum widthwise dimension.

2. The filter of Claim 1, wherein said pores are about 20-200 microns in size.

3. The filter of Claim 1, wherein said flexible material comprises a nonelastomeric polymer.

4. The filter of Claim 1, wherein said flexible material comprises an elastomer.

5. The filter of Claim 1, wherein said body has an outer coating of an agent selected from the group consisting of heparin, hirudin, and pirudin.

6. A filter for use with a vascular occlusion device of the type having an elongated shaft and a filter deployment system located near a distal end of said shaft, said filter comprising:

a hollow body made of a flexible material, said body having a proximal end and a distal end, said body having a region of maximum widthwise dimension located between said proximal end and said distal end, said body tapering from said proximal end to said region of maximum widthwise dimension and from said region of maximum widthwise dimension to said distal end; and

a number of pores in said body, said pores being sized to prevent emboli from flowing past said distal end when said filter is employed in the vasculature of a patient;

wherein said body has a proximal face located proximal of said region of maximum widthwise dimension and a distal face located distal of said region of maximum widthwise dimension, said proximal face having a number of cutouts which are each large in size relative to any of said pores, at least some of said number of pores being formed in said distal face.

7. The filter of Claim 6, wherein said pores are about 20-200 microns in size.

8. The filter of Claim 6, wherein said flexible material comprises a nonelastomeric polymer.

9. The filter of Claim 6, wherein said flexible material comprises an elastomer.

10. The filter of Claim 6, wherein said flexible material comprises a mesh constructed of a material selected from the group consisting of polyurethane, nylon, polyester, and polyethylene.

11. The filter of Claim 6, wherein said flexible material comprises a nylon, polyester or nitinol braid.

12. The filter of Claim 6, wherein said body has an outer coating of an agent selected from the group consisting of heparin, hirudin, and pirudin.

13. A filter for use with a vascular occlusion device of the type having an elongated shaft and a filter deployment system located near a distal end of said shaft, said filter comprising:

a hollow body made of a flexible material, said body having a proximal end and a distal end, said body having a region of maximum widthwise dimension located between said proximal end and said distal end, said body tapering from said proximal end to said region of maximum widthwise dimension and from said region of maximum widthwise dimension to said distal end; and

a number of pores in said body, said pores being sized to prevent emboli from flowing past said distal end when said filter is employed in the vasculature of a patient;

wherein said number of pores comprises one or more longitudinally aligned pairs of pores.

14. The filter of Claim 13, wherein said pores are about 20-200 microns in size.

15. The filter of Claim 13, wherein said flexible material comprises a nonelastomeric polymer.

16. The filter of Claim 13, wherein said flexible material comprises an elastomer.

17. The filter of Claim 13, wherein said body has an outer coating of an agent selected from the group consisting of heparin, hirudin, and pirudin.

18. A vascular occlusion device, comprising:

a shaft having a distal end and a proximal end;

a filter subassembly attached to said distal end of said shaft and having a distal end and a proximal end, said filter subassembly comprising an expandable support and a filter suspended on said expandable support, said filter comprising

a first cup made of a flexible material, said first cup having a proximal end and a distal end, an opening at said proximal end, and a region of maximum widthwise dimension adjacent said opening, said first cup tapering from said region of maximum widthwise dimension to said distal end;

a second cup made of a flexible material, said second cup having a proximal end and a distal end, an opening at said distal end, and a region of maximum widthwise dimension adjacent said opening, said second cup tapering from said region of maximum widthwise dimension to said proximal end;

a first set of pores in said first cup, said first set of pores being sized to prevent emboli from flowing past said distal end of said first cup when said filter is employed in the vasculature of a patient; and

a second set of pores in said second cup, said first set of pores comprising pores which are smaller in diameter than said second set of pores; and

a distal tip comprising a coil attached to said distal end of said filter subassembly.

19. The device of Claim 18, wherein said coil further comprises a distal end and a proximal end, and said expandable support comprises a number of radially expandable struts attached to said distal end of said shaft and to said proximal end of said coil.

20. A vascular occlusion device, comprising:

a shaft having a distal end and a proximal end;

a filter subassembly attached to said distal end of said shaft and having a distal end and a proximal end, said filter subassembly comprising a number of radially expandable struts attached to said distal end of said shaft and extending distally therefrom, and filter suspended on said struts;

a distal tip comprising a coil attached to said distal end of said filter subassembly; and

a web of flexible material attached to said distal end of said shaft and extending distally along said struts, so as to cover a proximal portion of said struts.

21. The device of Claim 20, wherein said web is substantially nonporous.

22. The device of Claim 20, wherein said web has an outer coating of an agent selected from the group consisting of heparin, hirudin, and pirudin.

23. The device of Claim 20, wherein said struts have an outer coating of an agent selected from the group consisting of heparin, hirudin, and pirudin.

24. The device of Claim 20, wherein said filter comprises:

a cup made of a flexible material, said cup having a proximal end and a distal end, an opening at said proximal end, and a region of maximum widthwise dimension adjacent said opening, said cup tapering from said region of maximum widthwise dimension to said distal end; and

a number of pores in said cup, said pores being sized to prevent emboli from flowing past said distal end when said filter is employed in the vasculature of a patient.

25. A vascular occlusion device, comprising:

a shaft having a distal end and a proximal end;

a filter subassembly attached to said distal end of said shaft and having a distal end and a proximal end; and

a distal tip comprising a coil attached to said distal end of said filter subassembly;

wherein said filter subassembly comprises:

a number of radially expandable struts attached to said distal end of said shaft and extending to a proximal end of said coil;

a first filter having an open proximal end attached to said struts and a closed distal end attached to said device at or near said coil;

a second filter having an open proximal end attached to said struts at a point distal of the point of attachment of said first filter to said struts, and a closed distal end attached to said device on or near said coil;

a first set of pores in said first filter; and

a second set of pores in said second filter, said second set of pores being smaller in diameter than said first set of pores.

26. The device of Claim 25, wherein said first set of pores and said second set of pores are about 20-200 microns in size.

27. The device of Claim 25, wherein said first filter or said second filter comprises a mesh constructed of a material selected from the group consisting of polyurethane, nylon, polyester, and polyethylene.

28. The device of Claim 25, wherein said first filter or said second filter comprises a nylon, polyester or nitinol braid.

29. The device of Claim 25, wherein said first filter or said second filter is constructed from a nonelastomeric polymer.

30. The device of Claim 25, wherein said first filter or said second filter is constructed from an elastomer.

31. A vascular occlusion device, comprising:

a shaft having a distal end, a proximal end and an internal lumen;

a core wire having a distal end and a proximal end, said core wire being disposed within said lumen of said shaft and moveable longitudinally therein;

a coiled-wire mechanism having a proximal end attached to said shaft and a distal end attached to said core wire at a point distal of said distal end of said shaft, said coiled-wire mechanism being moveable between a radially collapsed and a radially expanded position by longitudinal or rotational movement of said core wire relative to said shaft; and

a filter membrane suspended on said coiled-wire mechanism.

32. The vascular occlusion device of Claim 31, wherein said coiled-wire mechanism comprises a single coiled wire.

33. The vascular occlusion device of Claim 31, wherein said coiled-wire mechanism comprises two or more coiled wires.

34. The vascular occlusion device of Claim 31, wherein said filter membrane has a number of pores of about 20-200 microns in size.

35. The vascular occlusion device of Claim 31, wherein said filter membrane is constructed from a nonelastomeric polymer.

36. The vascular occlusion device of Claim 31, wherein said filter membrane is constructed from an elastomer.

37. The vascular occlusion device of Claim 31, wherein said filter membrane has an outer coating of an agent selected from the group consisting of heparin, hirudin, and pirudin.

38. The vascular occlusion device of Claim 31, wherein said filter membrane comprises a mesh constructed of a material selected from the group consisting of polyurethane, nylon, polyester, and polyethylene.

39. The vascular occlusion device of Claim 31, wherein said filter membrane comprises a nylon, polyester or nitinol braid.

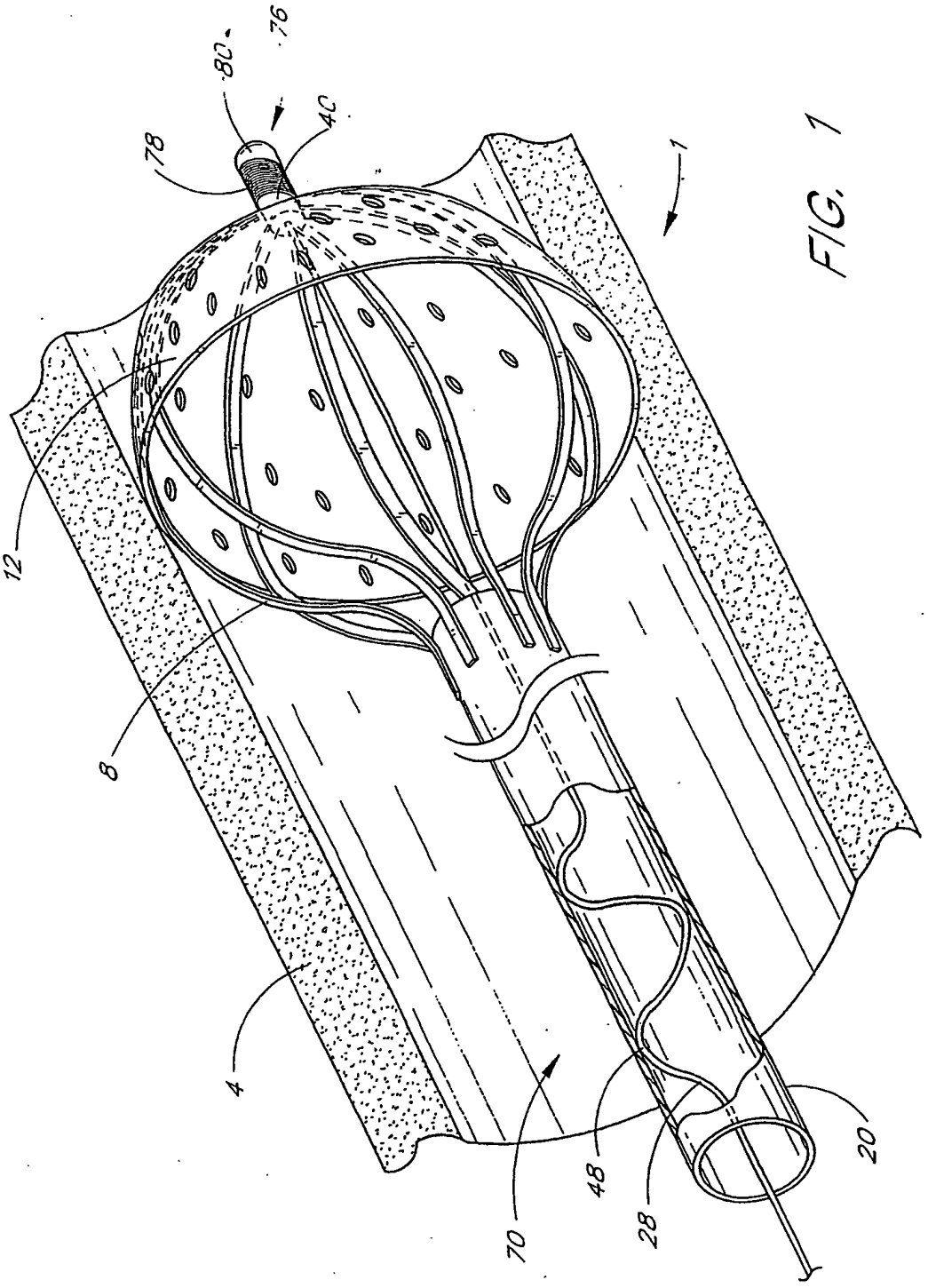


FIG. 1

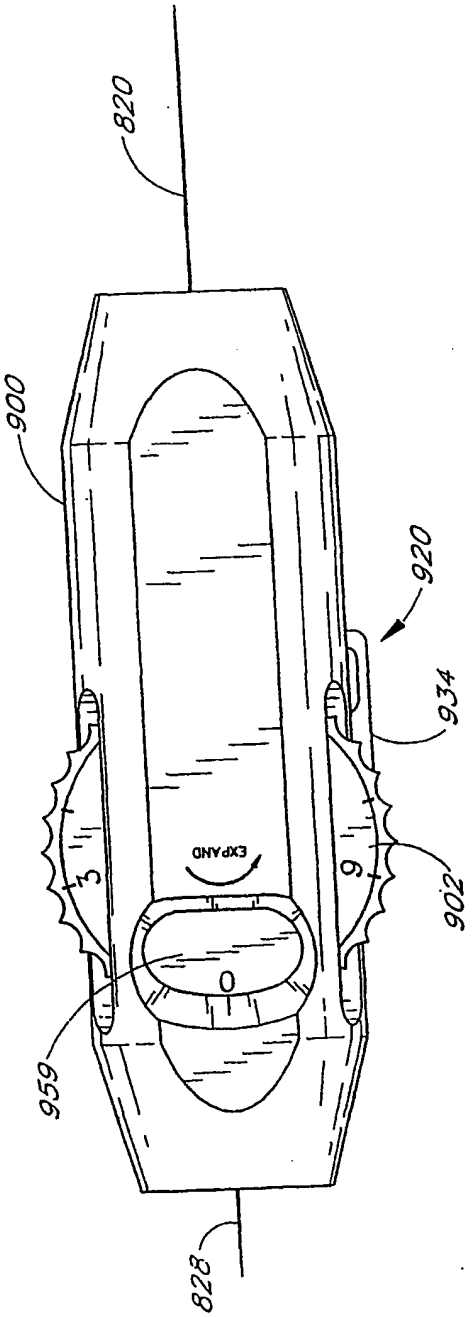
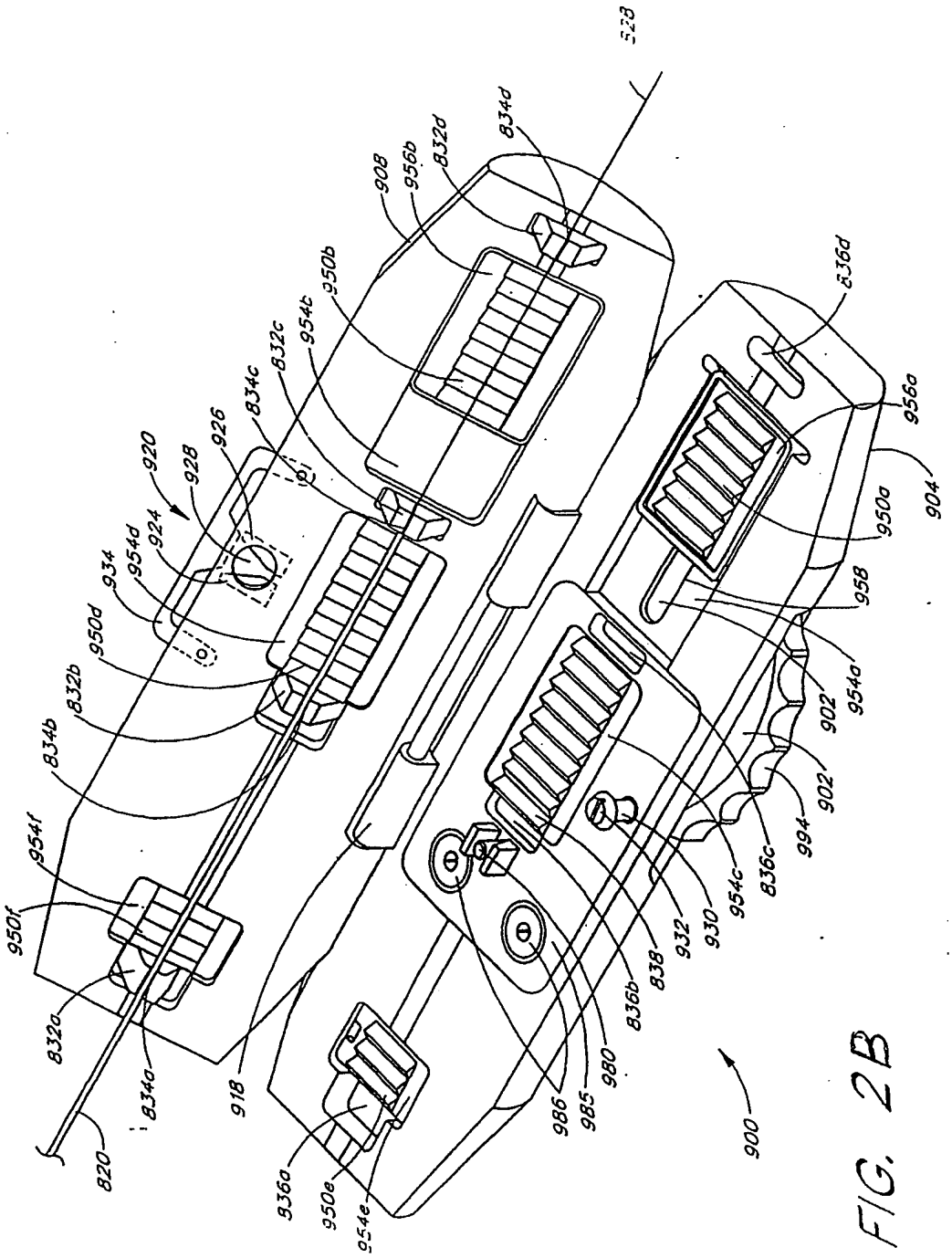


FIG. 2A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834d
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FIG. 2B

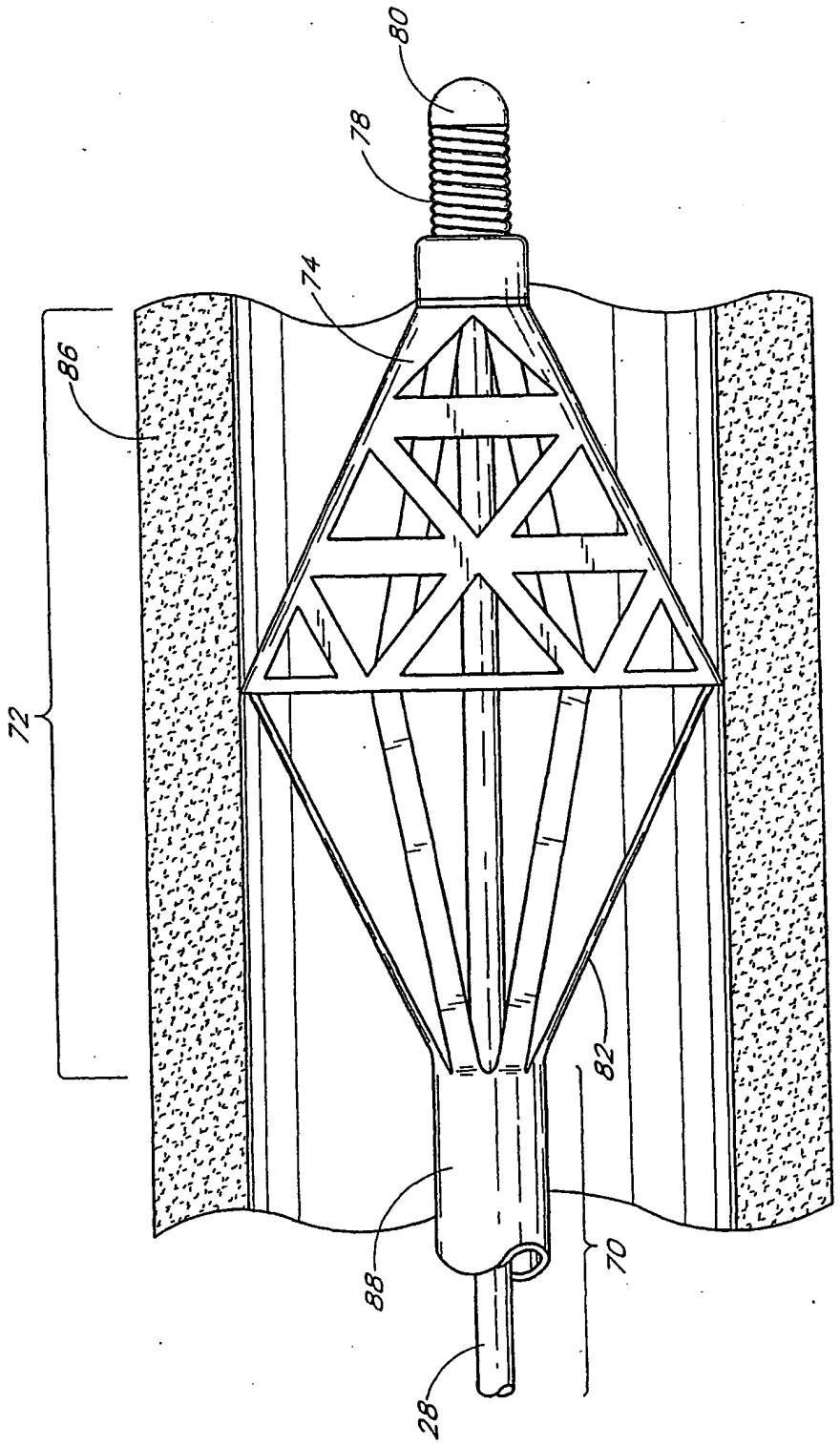

FIG. 3

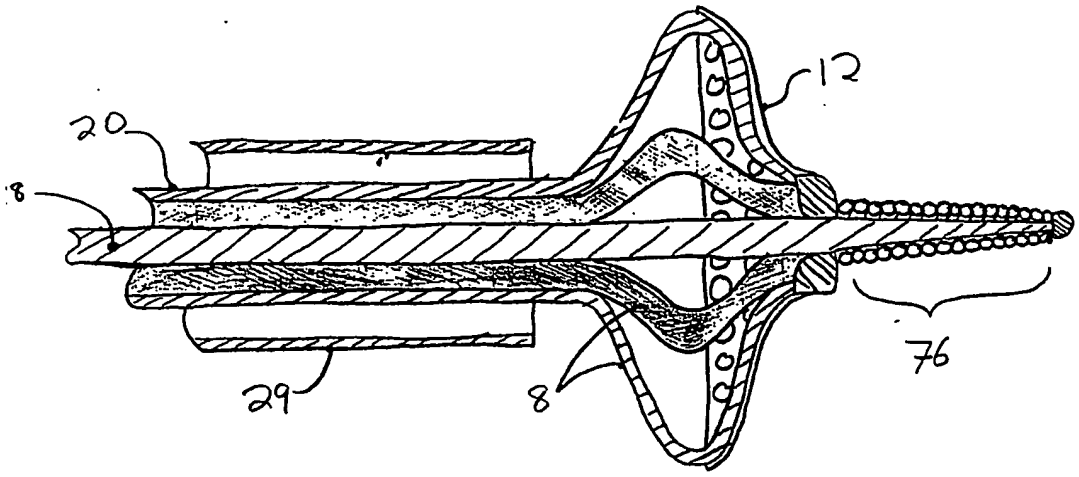

FIGURE 3A

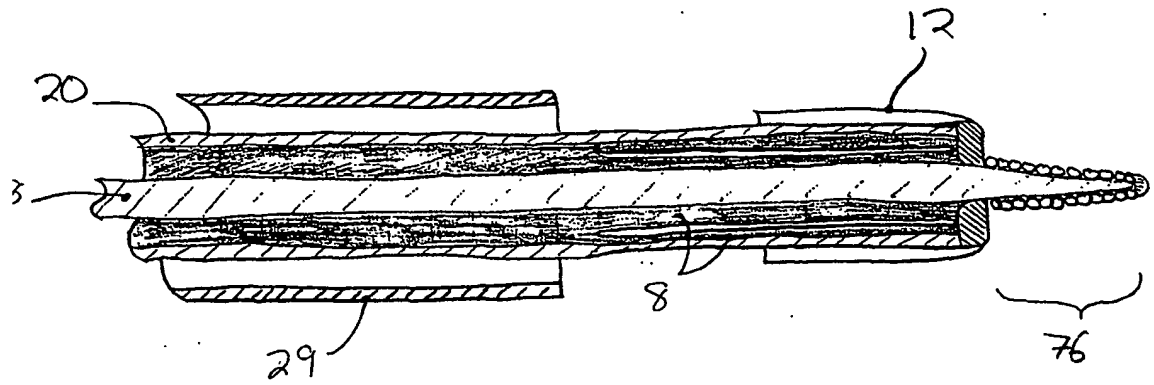

FIGURE 3B

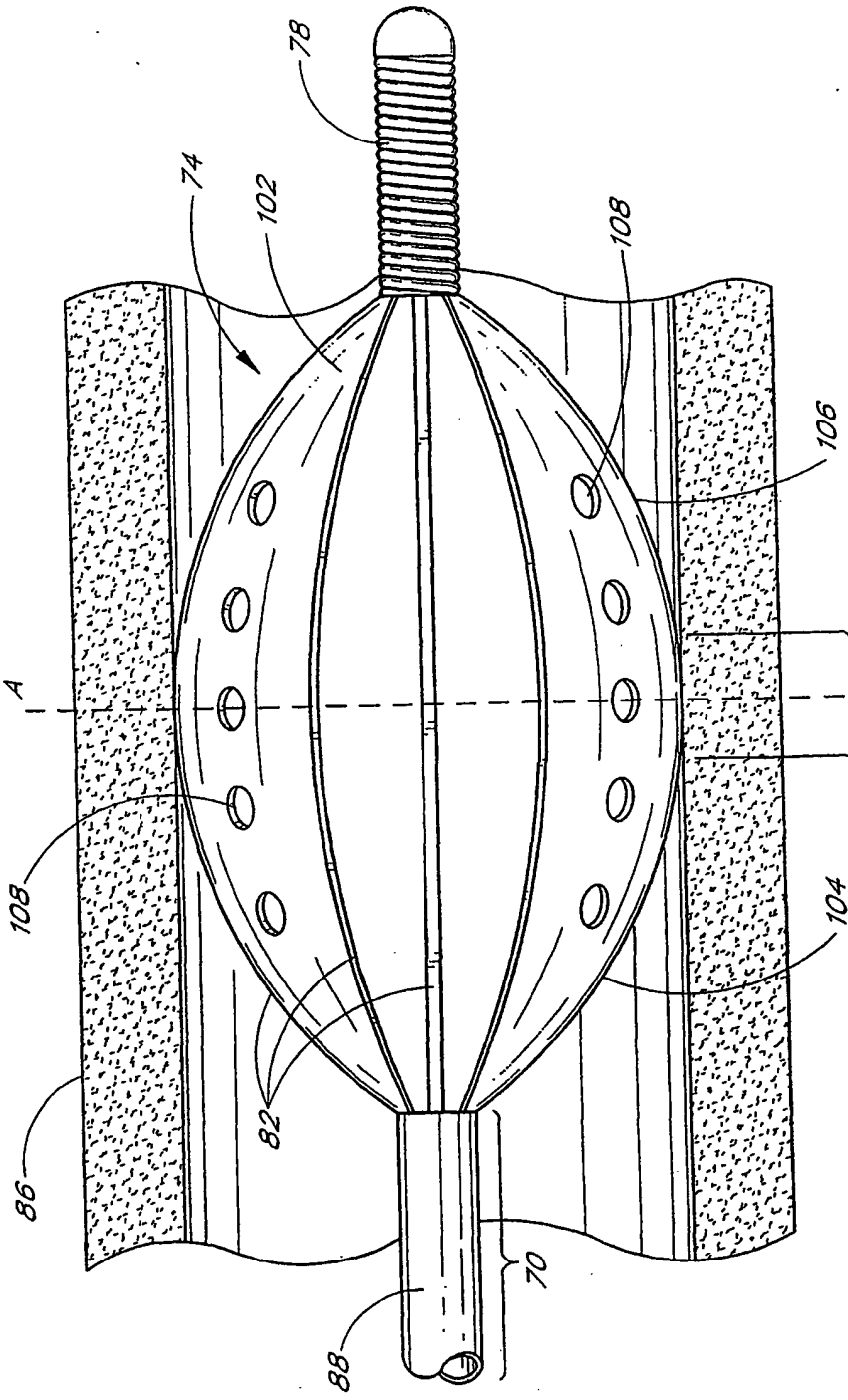

FIG. 4

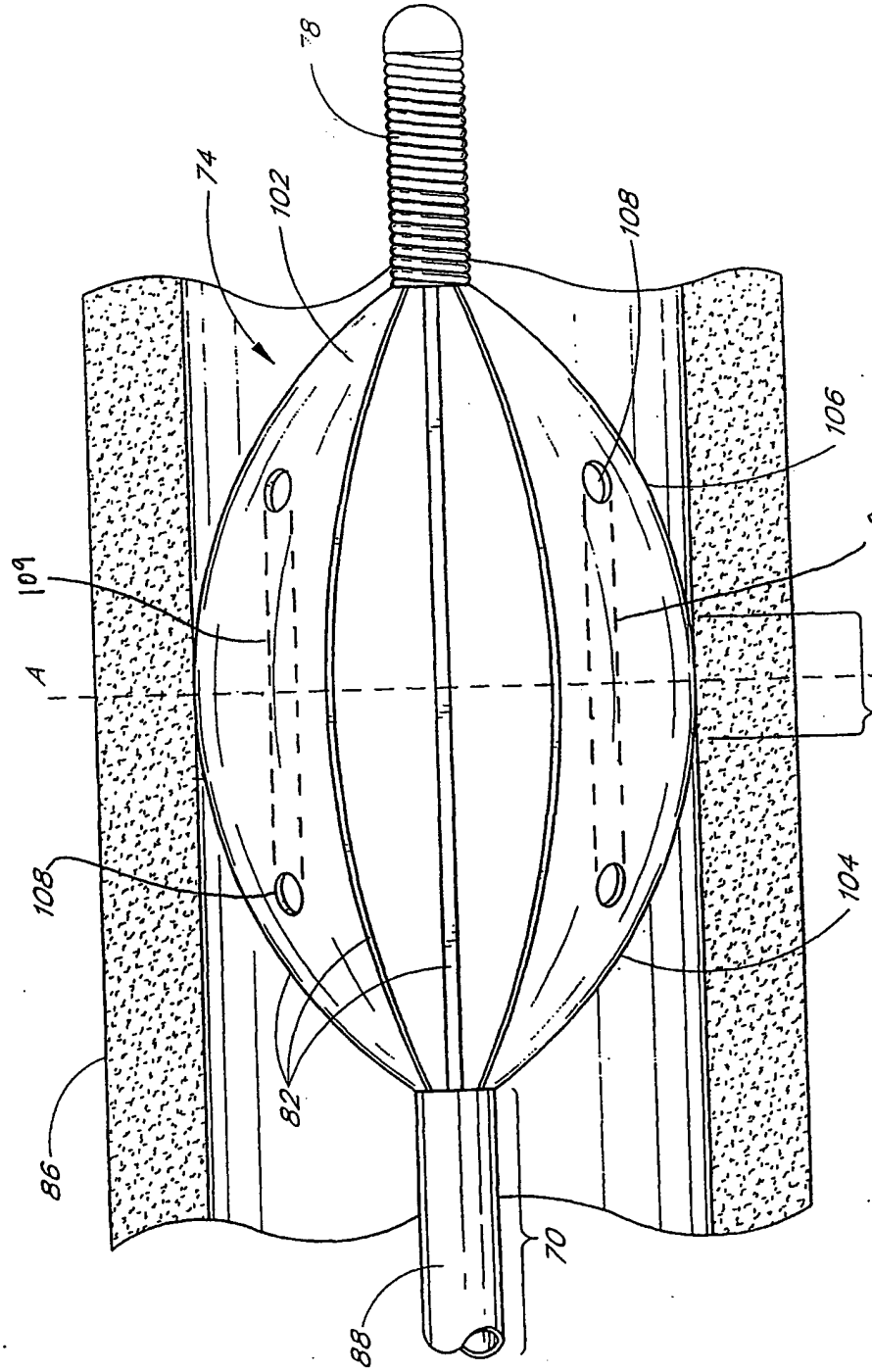

FIG. 4A

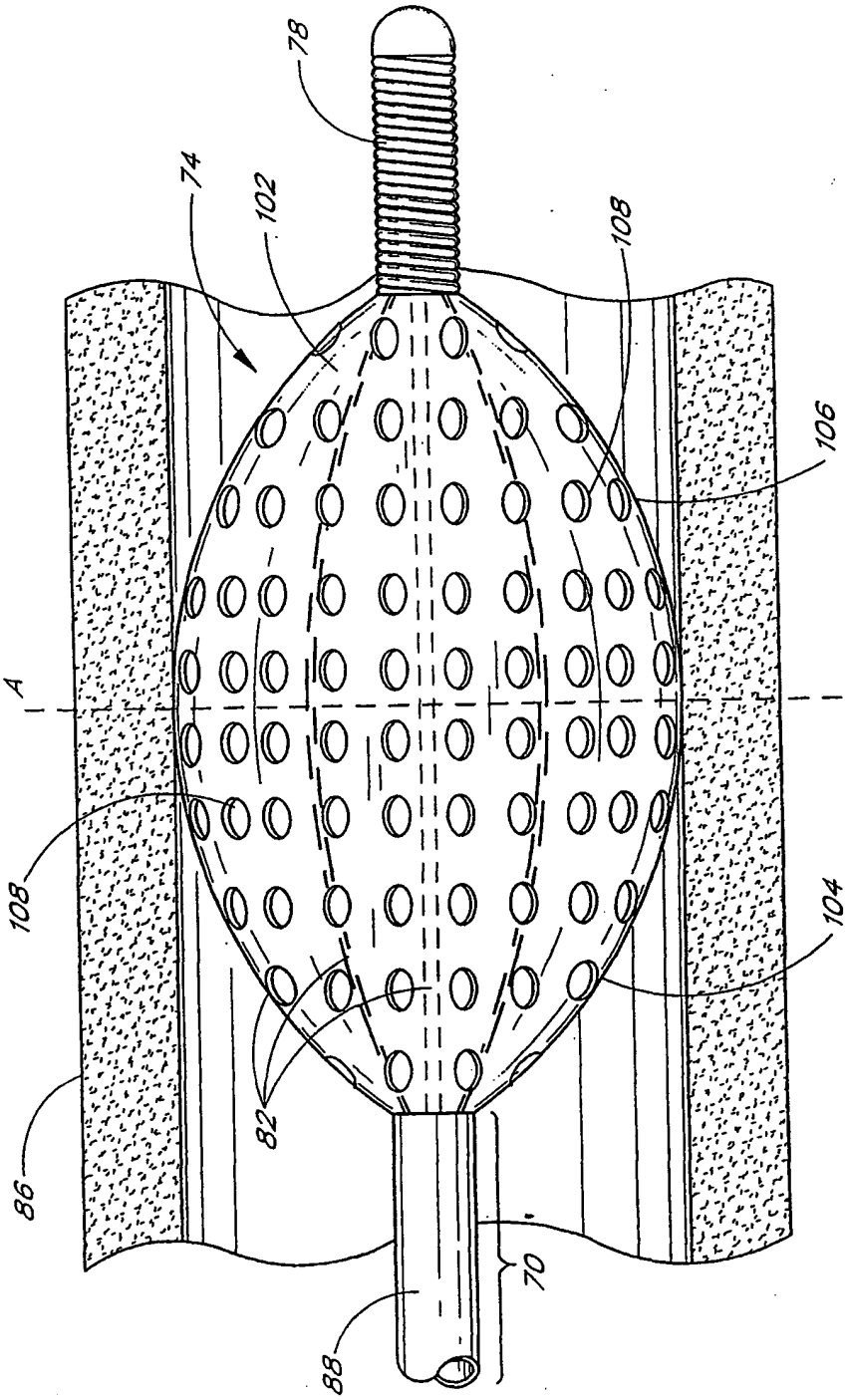

FIG. 5

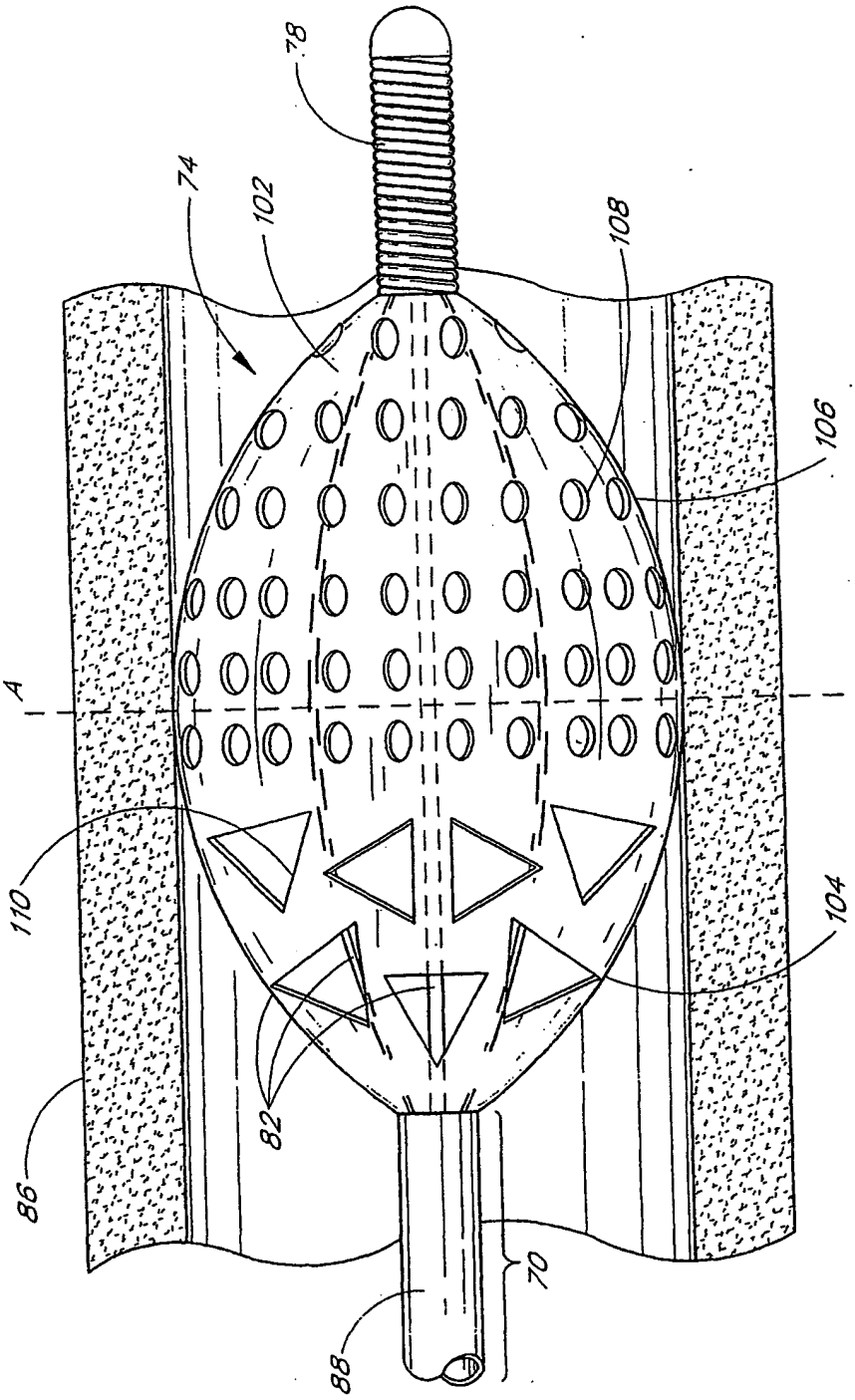

FIG. 6

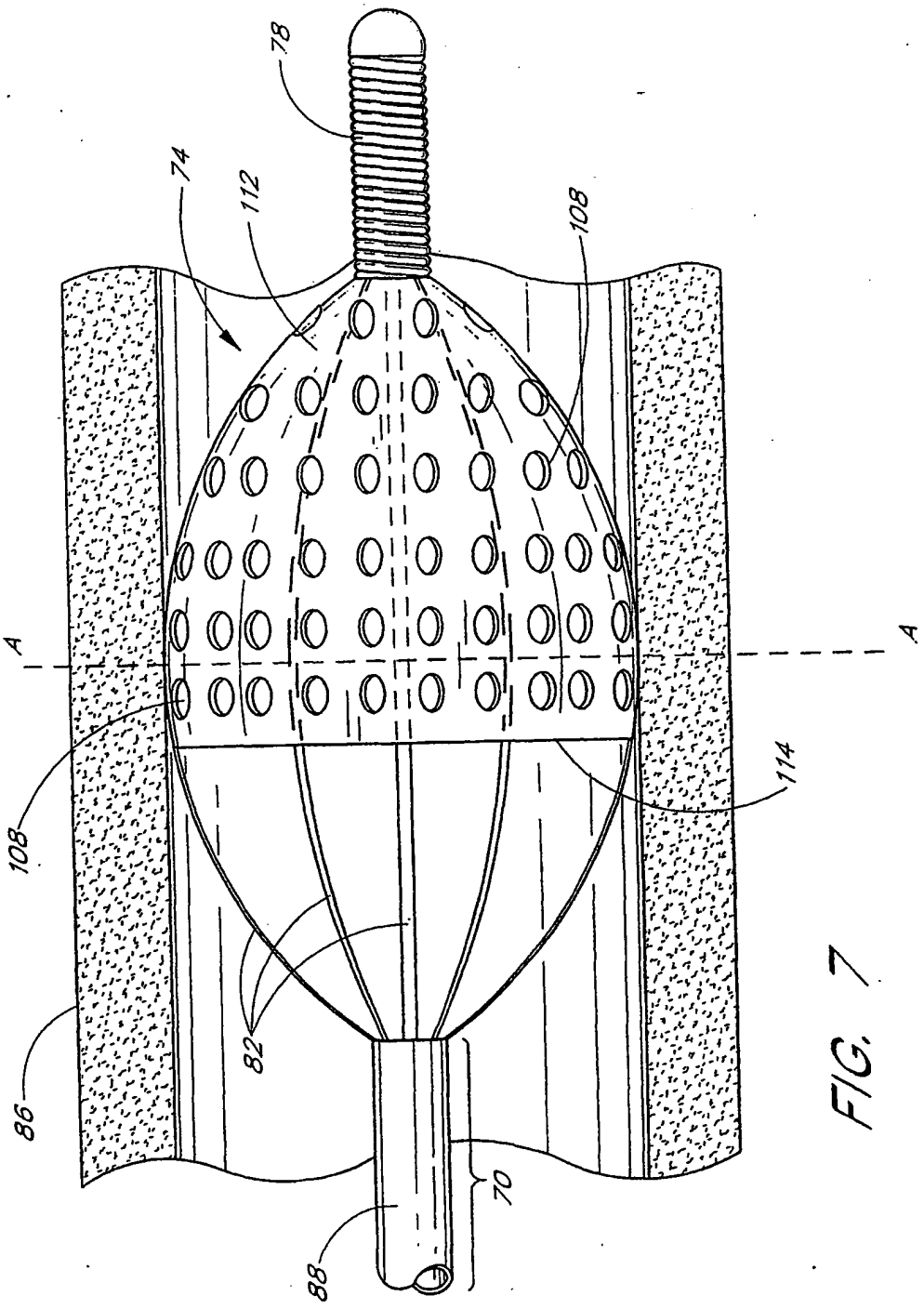

FIG. 7

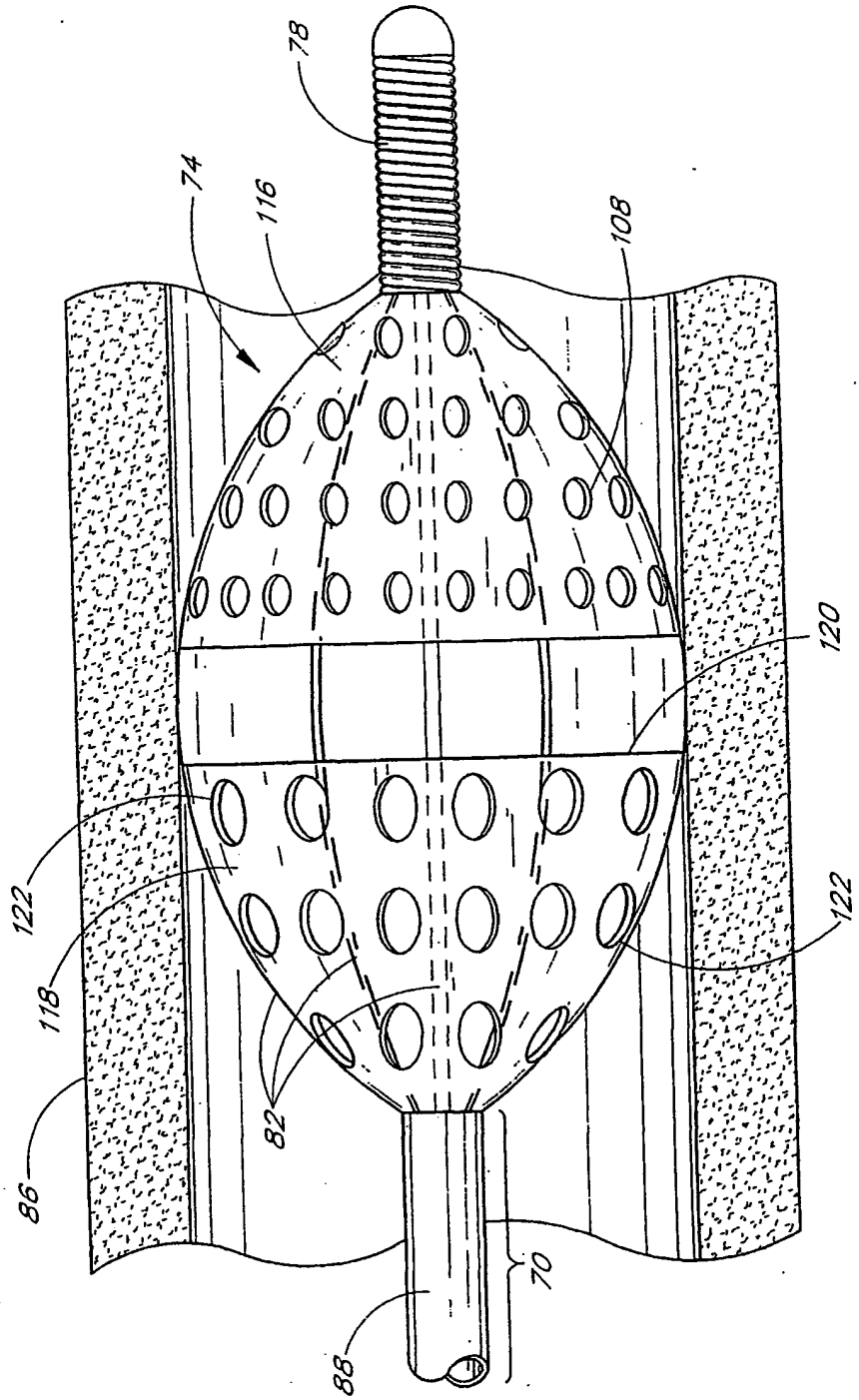

FIG. 8

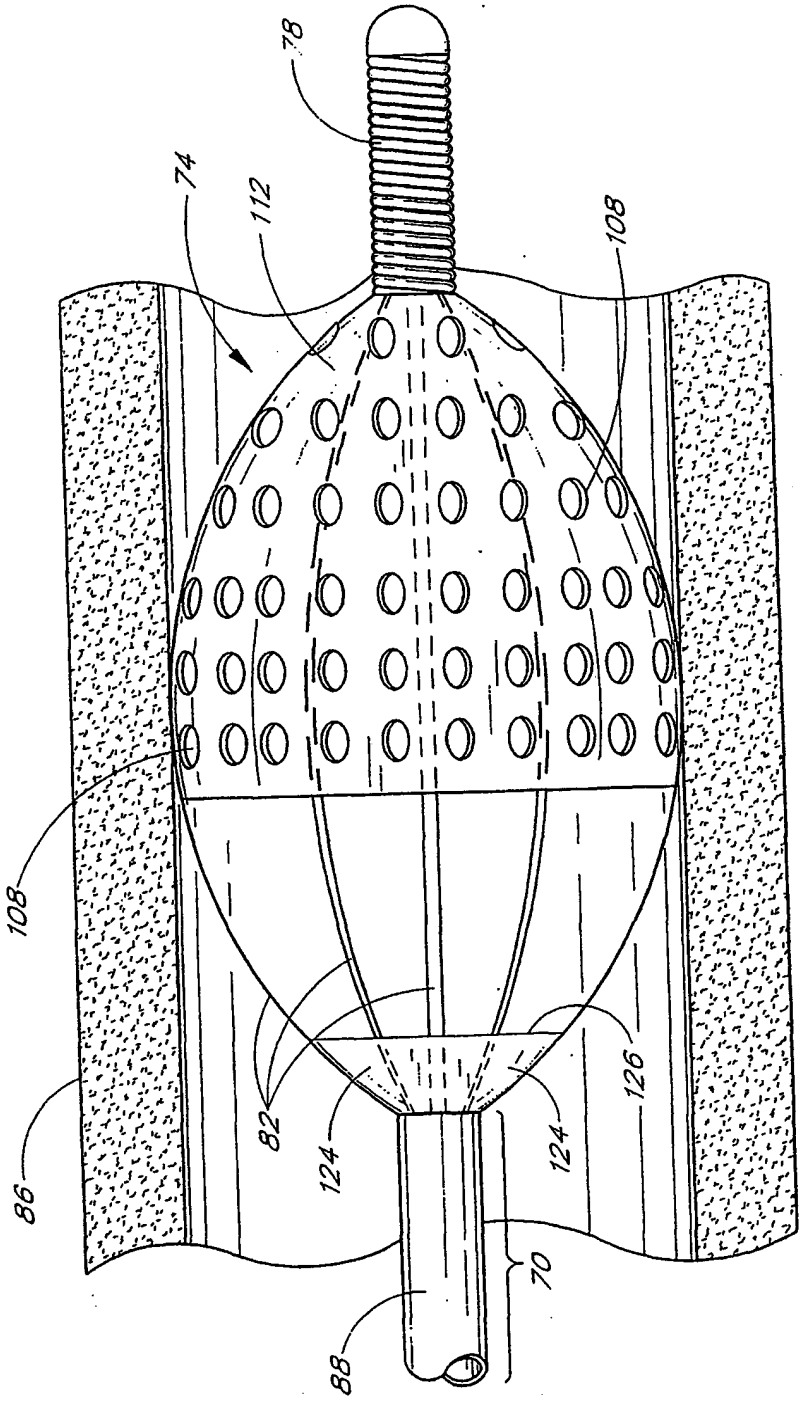

FIG. 9

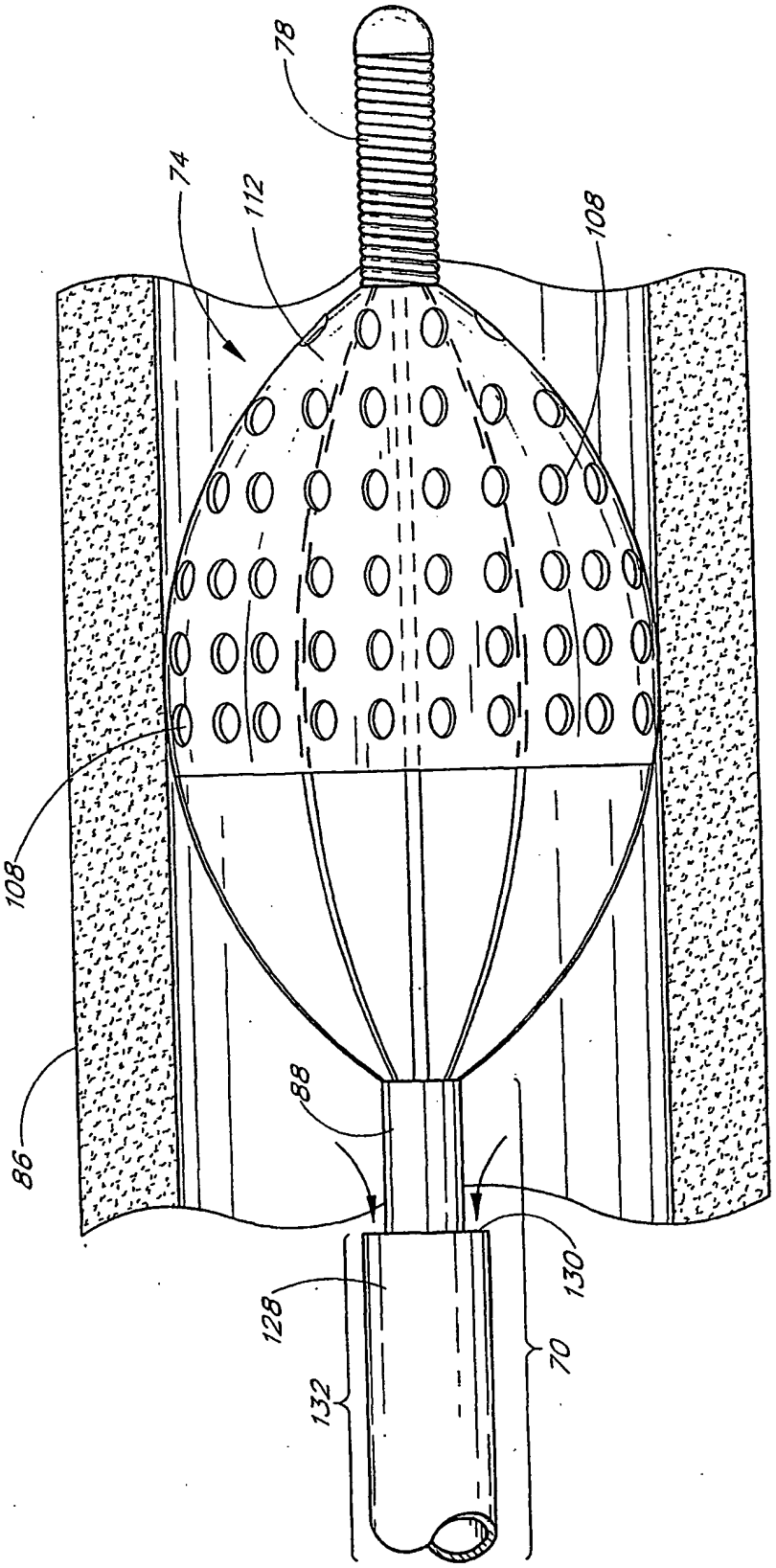

FIG. 10

PERCUS.137A

2 FILTERS IN SET OF STRUTS

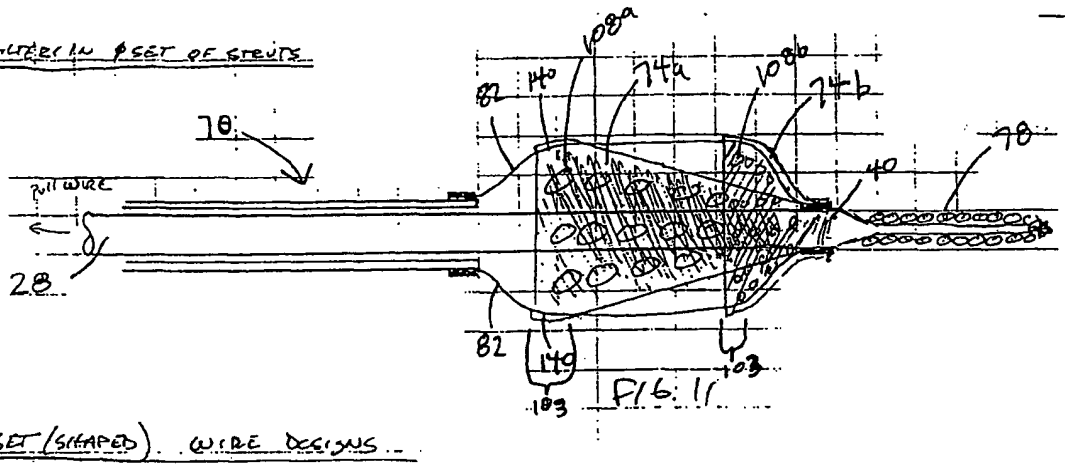

FIG. 11

PRE SET (SHAPED) WIRE DESIGNS

1 WIRE

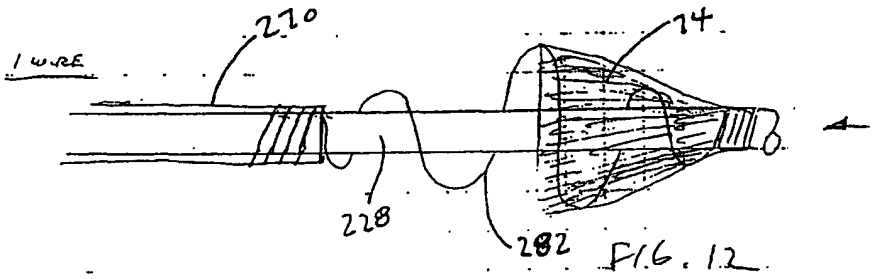

FIG. 12

2 WIRES

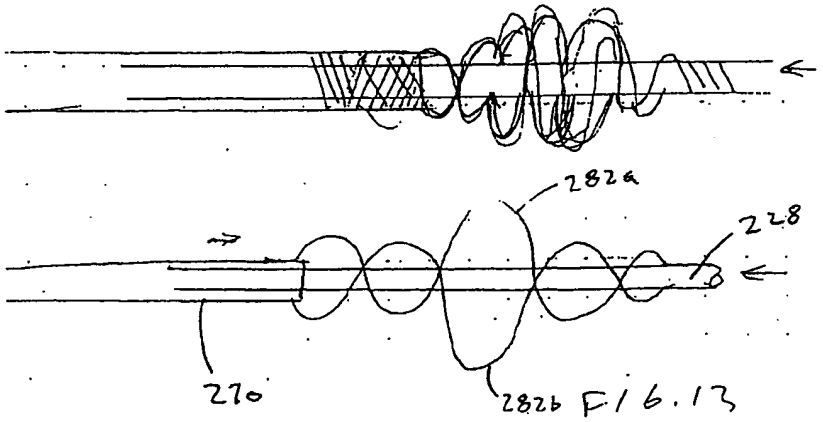

FIG. 13